



Neuspera Sacral Nerve Stimulator Implant Kit

Instructions for Use

MODEL: SNS-28

R_x only

Patent information covering this product is available at
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1 Description

The Neuspera Sacral Neuromodulation (SNM) System consists of an implantable stimulator (neurostimulator) that is operated by a Wireless Transmitter (WT) worn at the base of the patient's spine. The Wireless Transmitter is controlled by the Clinician Programmer and Patient Controller. The neurostimulator is a timed stimulator with four programmable electrodes.

The Neuspera Sacral Nerve Stimulator Implant Kit (Implant Kit) (Model SNS-28) contains the implantable neurostimulator and tools to introduce and implant the neurostimulator. The kit contains two guidewires, two foramen needles, a pre-dilator, a dilator/sheath assembly, and the neurostimulator and delivery push rod assembly.

- The foramen needle is used to locate an appropriate foramen, test stimulate the implantation location, and introduce the guidewire.
- The guidewire guides the path and depth of the two dilators.
- The pre-dilator provides initial dilation of the neurostimulator introduction pathway.
- The dilator/sheath assembly introduces the sheath to the correct location in the foramen and the sheath will introduce the neurostimulator.
- The neurostimulator/push rod assembly is used to place the neurostimulator correctly in the foramen through the sheath.

In addition to the kit, Wireless Transmitter, and Clinician Programmer, the following components are required for the implantation procedure:

- Basic surgical instruments to perform standard surgical procedures (incisions, surgical site closure, etc.) and aid in the removal of the neurostimulator, if needed.
- C-Arm Fluoroscopy equipment to visualize the anatomy and provide guidance for the placement of the

neurostimulator.

- An Intraoperative Cable, ground pad, and External Stimulator to perform functional mapping of the sacral nerve.

Refer to the Clinician Manual for additional components of the system used outside the implantation procedure.

2 Intended Use

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

3 Contraindications

- Patients with sacral depth measured from skin to the S3 foramen greater than 10 cm as confirmed by imaging.
- Patients who have not demonstrated an appropriate response to test stimulation
- Patients who are unable to operate the neurostimulator
- Men who have Benign Prostatic Hyperplasia (BPH) or patients with other lower urinary tract obstructions that leads to significant obstructive symptoms or pathology.

After implantation of the Neurostimulator, the following contradictions apply:

- Electrical treatments where the conducted current is induced into the body from an external source in the area of the Neurostimulator (this may permanently damage the Neurostimulator).
- Medical treatments or procedures utilizing effects caused by electric fields (such as diathermy) unless the treatment or procedure is identified within as acceptable (such as MRI).

4 Warnings

Do not detach or disassemble devices, or use accessories not described in this manual. The system may not function according to specification under these conditions.

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

Implant fracture or migration may occur. Patients should be monitored for potential fracture or migrations if they have any loss of stimulation.

Inform patients of the following warnings:

- Wearing the Wireless Transmitter against your skin may result in discomfort, irritation, or a burn.
- Do not place the Undergarment in direct contact with compromised skin such as open or healing wounds. Follow the instructions provided by your clinician for post operative wound care after implantation of the Neuspera neurostimulator.
- Do not use the Wireless Transmitter in situations where the temperature is very hot (above 35°C or 95°F) or in conditions where there is limited air circulation (such as under a blanket, heavy clothing, or in a heavily padded chair). Doing so could result in the Wireless Transmitter overheating. Burns or other injury could result.
- Do not use the Wireless Transmitter if you are unable to feel that the device is getting too hot, such as while sleeping. Burns or other injuries could result.

EMI from various sources may damage the device, interfere with device operation, or cause harm to the patient. Please consider the following:

- Defibrillation or Cardioversion
 - When a patient is in ventricular or atrial fibrillation, the first consideration is patient survival. External defibrillation or cardioversion can damage the Neurostimulator and cause induced currents in the

Neurostimulator that can injure the patient.

Minimize the current flowing through the Neurostimulator by following these guidelines:

- Position defibrillation paddles as far from the Neurostimulator as possible.
- Position defibrillation paddles perpendicular to the Neurostimulator.
- Use the lowest clinically appropriate energy (joules) output (watt seconds).
- After defibrillation, confirm the Neurostimulator is functioning as expected.
- Electrocautery
 - If electrocautery is used near an implantable device or contacts a device or insertion-needle, the following effects may occur:
 - The tissue surrounding the device may be damaged.
 - The Neurostimulator may be damaged, or stimulation may be temporarily suppressed or increased.
 - When electrocautery is necessary, follow these precautions:
 - Before using electrocautery, remove the Wireless Transmitter.
 - Bipolar cautery is recommended.
 - Keep at least 2 inches from the implant
 - If unipolar cautery is necessary, follow these guidelines:
 - Use only a low-voltage mode.
 - Use the lowest possible power setting.
 - Keep the current path (ground plate) as far from the Neurostimulator as possible.
 - Keep at least 2 inches from the implant
 - Do not use full-length operating room table grounding pads.
 - After using electrocautery, confirm that the Neurostimulator is functioning as intended.

- High-output ultrasonics or lithotripsy – Use of high-output ultrasonic devices, such as electrohydraulic lithotripters, is not recommended for patients who have an implanted Neurostimulator. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the Neurostimulator circuitry. If lithotripsy must be used, remove the Wireless Transmitter and do not focus the beam within 15 cm (6 in) of the Neurostimulator.
- Radiofrequency (RF) or microwave ablation – Safety has not been established for RF or microwave ablation in patients who have an implanted Neurostimulator. Induced electrical currents may cause heating of the Neurostimulator resulting in tissue damage. Effects of monitoring devices – When using diagnostic monitoring devices such as an electrocardiogram (ECG), Holter Monitor, or electroencephalogram (EEG), have the patient remove the Wireless Transmitter as pulses from the Neurostimulator may be detected as an electrical signal.
- Theft detectors and security screening devices

Note: Some theft detectors and screening devices may not be visible.

- Theft detectors found in retail stores, public libraries, etc., and security screening devices found in airports, government buildings, etc., may occasionally cause a momentary change in stimulation. When passing through these devices while wearing the Wireless Transmitter, some patients may perceive intermittent stimulation as therapy is switching on and off. It is also possible that patients, especially those that have low stimulation levels, may feel a momentary change in stimulation when they pass through these devices.
- When approaching these devices, patients should do the following:
 - If possible, instruct patients to request to bypass these devices. Security personnel may

use a handheld security wand but patients should ask the security personnel not to hold the security wand over the Neurostimulator any longer than is absolutely necessary. Patients may wish to ask for another form of personal search.

- If patients must pass through the theft detector or security screening device, they should turn off or remove their Wireless Transmitter.
- If two security gates are present, they should walk through the middle at a normal pace, keeping as far from each gate as possible.
- If one gate is present, they should walk as far from it as possible.
- Proceed through the security device at a normal pace. Patients should not lean or linger on the screening device.
- After patients pass through the security device, they should re-enable therapy.

5 Precautions

(see also the EMI Precautions section)

- Prior to use, clinicians should be trained on the implantation procedure and use of the Neuspera SNM System.
 - Implanting clinicians should be trained on sacral nerve stimulation (SNS), the implantation procedure, and use of the Neuspera SNM System. A formal training program, including both a didactic session and a hands-on training lab, will be provided for the Neuspera SNM System; clinicians will be required to pass a formal knowledge assessment prior to implanting the device.
 - A Neuspera Field Clinical Engineer (FCE) is required to be present at each implantation procedure. Please contact your local sales representative or call (888) 846-8332 or email Physicianhelp@neuspera.com to

ensure an FCE will be present at the procedure.

- Prescribing clinicians should be experienced in the diagnosis and treatment of lower urinary tract symptoms and should be trained on the use of the Neuspera SNM System.
- The Neuspera Sacral Nerve Stimulator Implant Kit and External Nerve Stimulator Kit are single use only. Reuse of these devices may result in patient harm including, but not limited to, systemic infection.
- The implantation procedure requires use of fluoroscopy, and it is recommended that the fluoroscope documentation be consulted for applicable warnings, contraindications, etc.
- If rash or other adverse skin reactions occur, instruct the patient to stop using the device, and monitor the skin.
- External pressure used during some medical procedures may damage the Neurostimulator which may require surgery to replace the device. During x-ray procedures that require external compression around the implanted Neurostimulator, the x-ray equipment should be adjusted to limit the amount of pressure exerted on the Neurostimulator.
- Patients with broken or blistered skin or with poor circulation in the area of the Neurostimulator should not use the Neuspera SNM System unless skin is covered with a bandage or until the skin has healed. Use medical judgement to determine if patients with these conditions may be more susceptible to thermal injuries prior to applying the Wireless Transmitter.
- Non-clinical testing has demonstrated that the Neurostimulator is MR Conditional; see MRI Safety Information Section.
- The safety and performance of the neurostimulator has not been evaluated for use in the following:

- Patients with BMI > 40,
- Pregnant women,
- Pediatric patients,
- Bilateral stimulation with the permanent Neuspera SNM System (bilateral stimulation may be used with Trial System),
- Patients with neurologic cause of OAB such as 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 Neuspera System with an active implantable device.
- The Neuspera System has not been tested for compatibility with cardiac defibrillation.
- 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.

6 Adverse Events

In addition to the risks normally associated with minor surgery (e.g., side effects from anesthesia, post-procedural pain or discomfort), other adverse events may occur with implantation. Certain adverse events may necessitate surgical intervention.

- Adverse change in voiding function (bowel and/or bladder)
- 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
- Implant fracture/failure
- Implant migration

- 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, hemorrhage, and/or hematoma
- 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

7 Summary of Clinical Evaluations

7.1 Introduction

Neuspera conducted a clinical study (IDE number G190064) to determine the safety and effectiveness of the Neuspera Sacral Neuromodulation (SNM) System for the treatment of urinary urge incontinence (UUI). The study design and data are summarized below.

7.2 Study Design

The SANS-UUI pivotal study (“Neuspera pivotal study”) was a prospective, multi-center, single-arm study to evaluate the safety and effectiveness of the Neuspera SNM System in the treatment of UUI. The study included patients with UUI who failed, could not tolerate, or were not a candidate for more conservative treatments, and 128 patients were implanted with the Neuspera SNM System. The SANS-UUI pivotal study was conducted in 29 clinical sites in the U.S. and 2 sites in Europe. The study evaluates the safety and effectiveness of the Neuspera SNM System after all subjects reached their 6-month visit. Additional data was collected beyond 6 months, including secondary endpoints at 12 months; see Figures 1 and 2 for the patient follow-up timepoints. The primary effectiveness endpoint is defined as the

percentage of all patients with an attempted implant who experience an improvement in their UUI symptoms of at least 50% or more (“therapy responders”). A therapy responder is defined as experiencing ≥50% reduction in the number of UUI episodes at 6 months after implant, compared to number of UUI episodes at baseline. The primary safety endpoint is defined as the number of device-related SAEs through the 6-month post-implant visit.

Table 1 shows the inclusion and exclusion criteria for the study.

Table 1: Inclusion and Exclusion Criteria

General inclusion criteria:
1. Is willing and able to understand and has voluntarily signed and dated the current approved informed consent. 2. Is male or female 22 years of age or older. 3. Has a Body Mass Index (BMI) greater than or equal to 18 and less than or equal to 40 kg/m². 4. Is a good surgical candidate and is capable of participating in all testing and follow-up clinic visits associated with this clinical study and is capable of independently using the system components as described in the Patient Manual. 5. Is ambulatory and able to use toilet without assistance. 6. Has a diagnosis of UUI for greater than or equal to 6 months prior to the screening baseline visit date. 7. Has typical residual bladder volume <150 cc tested within 6 months prior to the screening baseline visit date or is willing to have a test at screening baseline visit. 8. Has urodynamic testing (uroflowmetry, cystometry, and pressure flow) completed within 6 months prior to the screening baseline visit date or is willing to have testing at the screening baseline visit. 9. Has cystoscopy testing completed within 6 months prior to the screening baseline visit date or is willing to have a test at the screening baseline visit. 10. Has failed or was not a candidate for more conservative treatment (e.g., pelvic floor exercise, biofeedback, behavioral modification)

11. Has failed, could not tolerate (stopped taking medication due to lack of efficacy or intolerable side effects), or not a good candidate for (as determined by treating physician) at least one (1) antimuscarinic or β_3 adrenoceptor agonist medication.
12. Is willing and able to washout (at least five half-lives) from OAB medications for a period determined appropriate based on type of OAB medication prior to the baseline bladder diary and remain off OAB medications through the 12-month follow-up visit.
13. Has appropriate sacral anatomy as determined by sponsor's and investigator's analysis of radiographic imaging. (The distance from the surface of the skin in the prone and seated position to the bone edge of the S3 foramen must be within the capabilities of the system).

Baseline Bladder Diary Inclusion Criteria:

14. Has a diagnosis of UUI with at least 4 UUI episodes on a 72-hour diary, and minimum of one (1) UUI episode per 24-hour period.

General exclusion criteria:

1. Has a hemoglobin A1c of >8%, or has diabetes mellitus with glucosuria.
2. Has diabetic neuropathy.
3. Has interstitial cystitis or bladder pain syndrome as defined by either American Urological Association (AUA) or European Association of Urology (EAU) guidelines, chronic pelvic pain, or recurrent symptomatic urinary tract infections.
4. Has skin, orthopedic, neurological, or hematological (bleeding disorder) or anatomical limitations that could prevent successful placement of the neurostimulator.
5. Has broken, blistered skin or compromised circulation in the area of the neurostimulator implant.
6. Has neurogenic bladder dysfunction such as traumatic or atraumatic myelopathy, multiple sclerosis, Parkinsonism, or history of cerebrovascular accident.

7. Has documented urinary retention within 6 months prior to the screening baseline visit date.
8. Has clinically significant bladder outlet obstruction.
9. Is currently undergoing or has previously undergone pelvic irradiation.
10. Is a subject with a mechanical obstruction such as benign prostatic hypertrophy, urethral stricture, or cancer.
11. Has current grade 3 or 4 pelvic organ prolapse including cystocele, rectocele, enterocele, procidentia, or vaginal vault prolapse.
12. Has symptomatic urinary tract infection (UTI); the subject may be considered for study enrollment if the subject is symptom-free after a full course of treatment prior to beginning the baseline bladder diary. If an asymptomatic bacteriuria is detected during the urinalysis performed at screening, a subject may be enrolled without a waiting period relative to UTI treatment.
13. Has primary stress incontinence or mixed incontinence where the stress component predominates or has been treated surgically for stress urinary incontinence within 6 months prior to the screening baseline visit date.
14. Has received tibial nerve stimulation (TNS) in the past 3 months for the treatment of overactive bladder or unwilling to stay off TNS therapy for 12-month period following implant.
15. Has received treatment of urinary symptoms with any botulinum neurotoxin type-A (BoNT-A) agent in the past 12 months; (e.g. onabotulinumtoxinA, Botox®, abobotulinumtoxinA, Dysport®, IncobotulinumtoxinA, Xeomin®).
16. Is a woman who is pregnant or planning to become pregnant during this clinical study or is a woman of child-bearing potential who is not using a medically acceptable method of birth control. Women of child-bearing potential must undergo a pregnancy test, with clear negative result.

17. Has active substance abuse, including alcohol.
18. Has a known hypersensitivity or contraindication to procedural or post-procedural medications which cannot be adequately managed medically.
19. Has a known hypersensitivity to Neuspera's SNS System device components.
20. Has previously failed SNS therapy.
21. Has active implantable medical devices such as neurostimulators, drug pumps, pacemakers, or internal defibrillators since compatibility has not been assessed.
22. Has known needs for diathermy (shortwave, microwave, or therapeutic ultrasound), and radiofrequency ablation in the vicinity of the neurostimulator since these procedures have not been evaluated.
23. Has a known need for therapeutic ultrasound in the area of the sacral nerve neurostimulator as the device can inadvertently concentrate the ultrasound field and cause harm.
24. Has a known need for therapeutic ionizing radiation as can damage the electrical components of the sacral nerve stimulator and any damage may not be immediately detectable.
25. Has plans to enroll or is currently enrolled in another investigational device or drug trial during his/her participation in this study.
26. The investigator is unable to elicit an appropriate motor response in the subject during the intra-operative testing of the implant procedure.

Patient Disposition

34 sites were activated, and 31 sites enrolled 242 patients. At 25 sites, 130 patients had implants attempted, and 128 patients were successfully implanted. See **Figure 1** for the patient disposition at the time of database lock for the 12-month analysis. At the time of the 12-month database lock, the reasons for withdrawal of enrolled subjects are summarized as follows: patients who did not meet eligibility criteria,

33.1% (80/242); withdrew consent, 10.3% (25/242); patients not satisfied with therapy, 3.7% (9/242); patients lost to follow-up, 2.5% (6/242); patients withdrawn by investigator, 1.7% (4/242); patients withdrawn as the sites were terminated by the sponsor, 1.7% (5/242); patients withdrawn due to adverse event, 1.2% (3/242); implant attempted but not completed, 0.8% (2/242); patient deceased, 0.4% (1/242); and were withdrawn for other reasons, 2.9% (7/242).

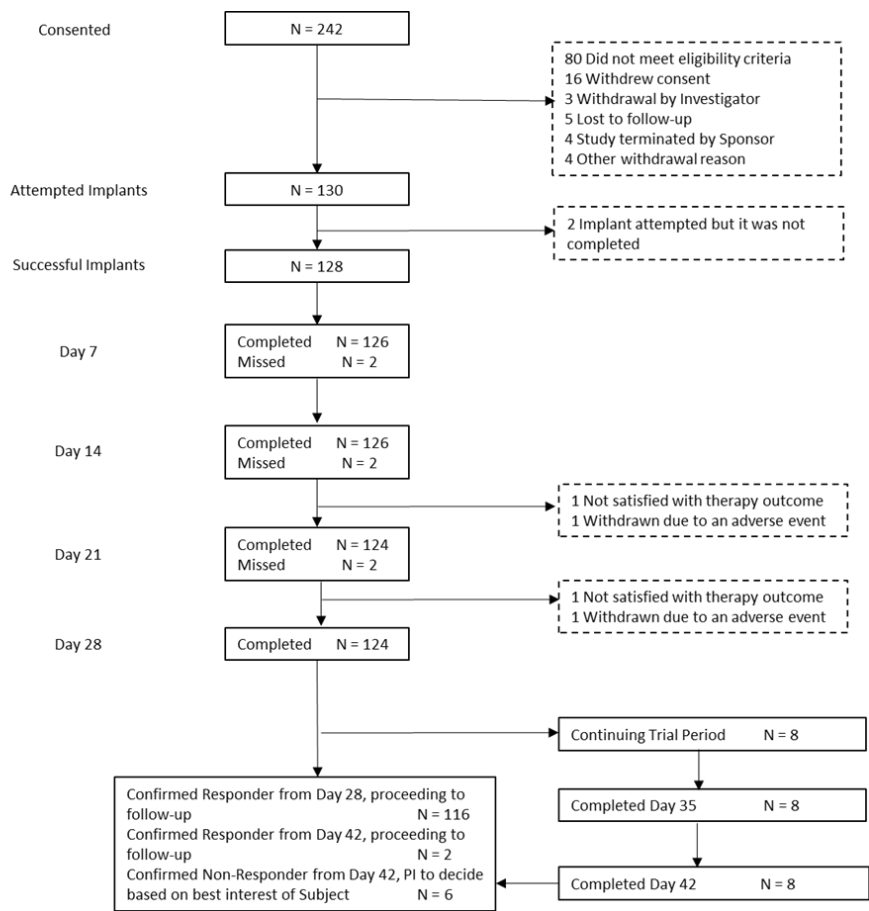


Figure 1: Patient Disposition – Post Implant Period

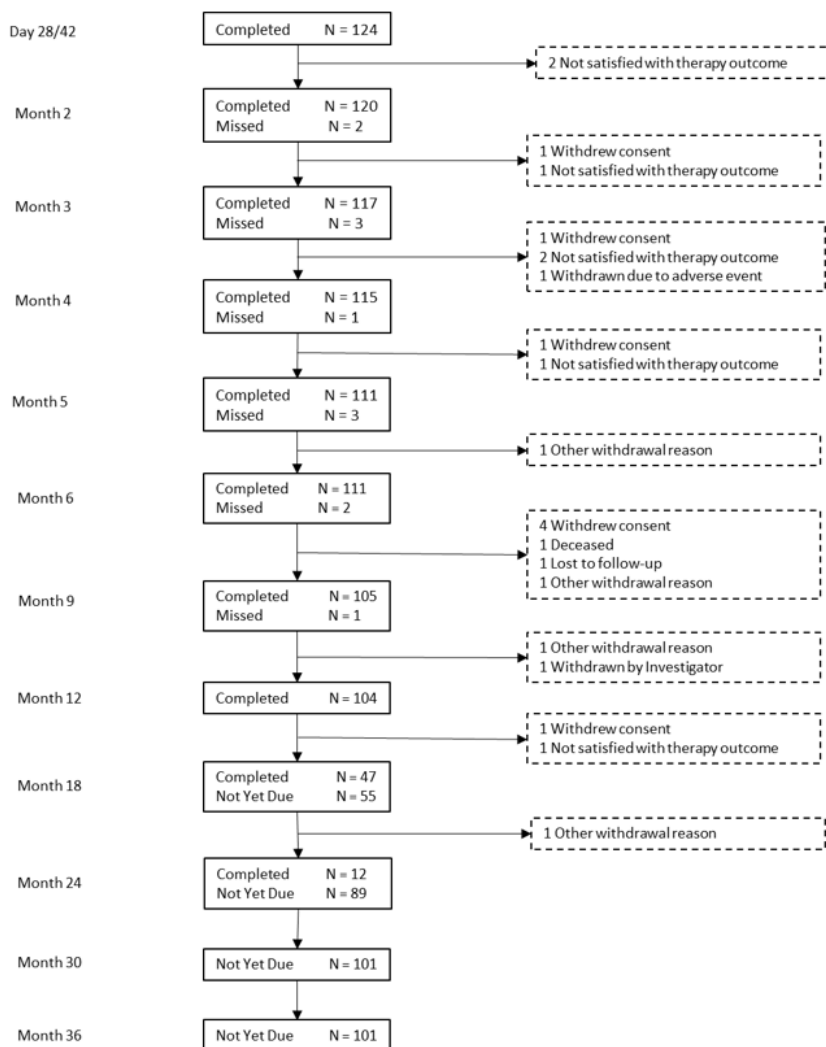


Figure 1: Patient Disposition – Post Implant Period (continued)

Analysis Sets

The analysis sets were pre-specified in the protocol as follows:

- **Intent-to-Treat (ITT) Analysis Set:** The ITT analysis set is defined as all patients who have signed informed consent.
- **Modified Intent-to-Treat (mITT) Analysis Set:** The modified Intent-to-Treat (mITT) Analysis Set is defined as all patients for whom an initial implant is attempted.
- **Implanted Analysis Set:** The Implanted analysis set is defined as all patients who are implanted with the Neuspera SNS system.
- **Responder Analysis Set:** The Responder analysis set is defined as patients who are implanted with the system and are defined as responders at the Day 28 or Day 42 clinic visit post-implant.
- **Per Protocol (PP) Analysis Set:** The Per Protocol analysis set is defined as implanted patients who have no protocol deviations that may significantly affect the primary endpoints. The determination of patients excluded from the Per Protocol analysis set was made prior to analysis.
- **Worst Case Analysis Set:** The Worst Case analysis set assumes that all patients with missing data were failures.

Patient Demographics and Baseline Characteristics

Demographics

Table 2 shows the baseline demographics of the mITT patients.

Table 2: Baseline Demographics

Baseline Characteristics	mITT (n = 130)
Age (years)	
N	130
Mean $\pm$ SD	60.4 $\pm$ 10.2
Median	61.0
Min, Max	21.0, 83.0
BMI	
N	130
Mean $\pm$ SD	29.5 $\pm$ 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)
Not Hispanic or Latino	120/130 (92.3)

Incontinence History

Table 3 presents the patients' incontinence history as reported at the baseline visit.

Table 3: 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	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

Patients in the mITT analysis set had a baseline of 4.5 ($\pm$ 2.5 SD) UUI episodes per day. See **Table 4** for the mITT patients categorized by severity of their UUI symptoms at baseline.

Table 4: 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 5 presents the patients’ UUI treatment history as reported at baseline.

Table 5: 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 demonstrated by a review of all Adverse Events (AEs). There were no device-related severe adverse events (SAEs) through the 12-month post-implant visit. There were a total of 338 adverse events in 108/130 (83.1%) patients, and 27 severe adverse events in 21/130 (16.2%) of patients in patients who had an attempted implant. One SAE was determined possibly related to the implant procedure. There were a total of 27 device-related events in 21 of 130 (16.2%) patients, and 21 procedure-related events in 19 of 130 patients (14.6%). Thirteen (13) events were definitely related to the device and one event definitely related to implant procedure.

There were 2 device fractures, 5 device migrations in 4 patients, 4 revisions, and 15 device explants at 6-months. At 12-months, there were a total of 5 device revisions and 21 explants. At 12 months, the number of device fractures and migrations did not change from 6 months. The majority of the migrations occurred within the first month of implant, and the fractures occurred on Day 26 and Day 63. However, one additional device fracture was seen after the 12-month data lock and was attributed to chiropractic manipulation. **Table 6** shows the

fractures, migrations, and revisions that occurred through the 12-month datalock.

Table 6: Fractures, Migrations, Revisions, and Explants through 12 months post-implant

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

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

Table 7 shows the device-related adverse events, and **Table 8** shows the procedure-related adverse events through the 12-month post-implant visit.

Table 7. Device-Related Adverse Events through 12-months post-implant – mITT Analysis Set (N = 130)

	Events n	Patients n/N (%)²
Total Device-Related Adverse Events¹	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 8: Procedure-Related Adverse Events through 12 months post-implant – mITT Analysis Set (N = 130)

	Events n	Patients n/N (%)²
Total Procedure-Related Adverse Events¹	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%)

¹As coded by the Clinical Events Committee chairperson.

² Exact 95% confidence Interval.

Table 9 shows device-related AEs as a function of time after implant through the 12-month visit database lock.

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

Device-Related AEs	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
Radicular pain			1				1
Urinary tract infection						1	1
Vulvovaginal pain		1					1

Table 10 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 10: 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
Mouth ulceration	1							1
Pain in extremity		1						1
Procedural headache		1						1
Radicular pain			1					1

Respiratory failure		1						1
Vomiting	1							1
Vulvovagina l pain		1						1

Effectiveness Result

Six-Months Results (Primary Endpoint)

For patients with an attempted implant (N=130), 82.9% of patients at Month 6 were responders ($\geq 50\%$ reduction from baseline in UIIs per day). The study met the 50% performance goal at 6 months, as summarized in **Table 11** below.

Table 11. Responder Rate in UII Summary at Month 6 – mITT Analysis Set (n=130) - Imputed

	Estimate (%)	Lower 95% CI	Upper 95% CI	P-value (2-sided)
Patients with $\geq 50\%$ reduction from baseline in UIIs per day	82.9%	76.4%	89.4%	<0.0001

Note: The imputation model includes baseline age, investigational site, baseline UII episodes, and all available follow-up visit UII episodes through 6 months. It uses full conditional specification and 100 imputed data sets.

The primary endpoint was also analyzed for additional study groups at 6 months, as summarized in **Table 12** below.

Table 12. Primary Endpoint for Various Analysis Sets at Month 6 - Imputed

Patients with $\geq 50\%$ reduction from baseline in UIIs 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. The estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

Note: The imputation model includes baseline age, investigational site, baseline UU/ episodes, and all available follow-up visit UII episodes through 6 months. It uses full conditional specification and 100 imputed data sets.

Table 13 presents data imputed for primary endpoint sub-group analysis at 6 months, based on the responder rate for UII episodes, for sex, age, race, baseline UII episodes and geographic region.

Table 13: Primary Endpoint Subgroup Analysis at Month 6 – mITT Analysis Set (N = 130) - Imputed

Patients with ≥ 50% reduction from baseline in UIIs per day	Estimate (%)	Lower 95% CI	Upper 95% CI³
Female (N=128)	82.6%	76.0%	89.2%
Male ¹ (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 UIIs <8 (N=117)	84.4%	77.8%	91.0%
Baseline UIIs ≥8 ² (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%

¹The subgroup does not contain any missing response values following the imputation of failures. Therefore, the estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

²The subgroup contains a single missing response value. The imputation model results in zero between-imputation variance. Therefore, the single missing value is imputed with the result of the multiple imputation value for that patient, and estimate is based on the data summary without multiple imputation modelling. Z-test statistic is displayed instead of t.

³If the imputation results in an upper 95% CI >100%, the value will be forced at 100%. Note: The imputation model includes baseline age, investigational site, baseline UII episodes, and all available follow-up visit UII episodes through 6 months. It uses full conditional specification and 100 imputed data sets.

Table 14 shows the secondary effectiveness endpoints related to urinary symptoms at 6 months.

Table 14. Secondary Effectiveness Results at Month 6 – mITT Analysis Set (N=130) - Imputed

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

The imputation model includes baseline age, investigational site, baseline data, and all available follow-up measures through 6 months. It uses full conditional specification and 100 imputed data sets.

For the secondary effectiveness endpoints in **Table 14**, the first three endpoints (i.e., reduction from baseline in the mean number of UUI episodes per day, improvement from baseline in ICIQ-OABqol score, and the percentage of patients who experienced an improvement in ICIQ-OABqol of at least 10 points) supported the findings from the primary endpoint in improvement in 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 patients with an attempted implant (N=130), 77.7% of patients at Month 12 were responders ($\geq 50\%$ reduction from baseline in UIIs per day), as summarized in **Table 15** below.

Table 15. Responder Rate in UII Summary at Month 12 – mITT Analysis Set (n=130) - Imputed

	Estimate (%)	Lower 95% CI	Upper 95% CI
Patients with $\geq 50\%$ reduction from baseline in UIIs per day	77.7%	70.4%	85.0%

Note: The imputation model includes baseline age, investigational site, baseline UII episodes, and all available follow-up visit UII episodes through 12 months. It uses full conditional specification and 100 imputed data sets.

This endpoint was also analyzed for additional study groups, as summarized in **Table 16** below.

Table 16. Responder Rate for Various Analysis Sets at Month 12 - Imputed

Patients with $\geq 50\%$ reduction from baseline in UIIs 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%

¹The worst case assumes all missing responses are failures. The estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

Note: The imputation model includes baseline age, investigational site, baseline UII episodes, and all available follow-up visit UII episodes through 12 months. It uses full conditional specification and 100 imputed data sets.

Table 17 presents data imputed for primary endpoint sub-group analysis at 12 months, based on the responder rate for UII episodes, for sex, age, race, baseline UII episodes and geographic region.

Table 17: Responder Rate Endpoint Subgroup Analysis at Month 12 – mITT Analysis Set (N = 130) - Imputed

Patients with ≥ 50% reduction from baseline in UUIs per day	Estimate (%)	Lower 95% CI	Upper 95% CI³
Female (N=128)	77.4%	70.0%	84.8%
Male ¹ (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 ¹ (N=7)	57.1%	20.5%	93.8%
Baseline UUIs <8 (N=117)	79.5%	72.0%	87.0%
Baseline UUIs ≥8 ² (N=13)	61.5%	35.1%	88.0%
US (N=124)	77.5%	70.0%	85.0%
EU ¹ (N=6)	83.3%	53.5%	100.0%

¹The subgroup does not contain any missing response values following the imputation of failures. Therefore, the estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

²The subgroup contains a single missing response value. The imputation model results in zero between-imputation variance. Therefore, the single missing value is imputed with the result of the multiple imputation value for that subject, and estimate is based on the data summary without multiple imputation modelling. Z-test statistic is displayed instead of t.

³If the imputation results in an upper 95% CI >100%, the value will be forced at 100%.
Note: The imputation model includes baseline age, investigational site, baseline UUI episodes, and all available follow-up visit UUI episodes through 12 months. It uses full conditional specification and 100 imputed data sets.

Table 18 shows the secondary effectiveness endpoints related to urinary symptoms at 12 months post-implant.

Table 18. Secondary Effectiveness Results at Month 12 – mITT Analysis Set (N=130) - Imputed

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

The imputation model includes baseline age, investigational site, baseline UUI episodes, and all available follow-up visit UUI episodes through 12 months. It uses full conditional specification and 100 imputed data sets.

7.3 Conclusions

Effectiveness Conclusions

The results from the SANS-UUI study show that SNM therapy provides a clinically meaningful improvement in symptoms of urge urinary incontinence in patients who have failed, could not tolerate, or were not a candidate for more conservative treatments. For the mITT analysis set, 82.9% and 77.7% of patients had a ≥ 50% reduction from baseline in UUIs per day at 6 months and 12 months post-implant, respectively.

The secondary effectiveness endpoints in the clinical study as measured by improvements in urinary symptoms including reduction in UUI episodes and ICIQ-OABqol scores also supported improvement in symptoms of UUI by the Neuspera SNM System.

Safety Conclusions

In the SANS-UUI study of the Neuspera SNM System, there were no serious device-related AEs and one serious procedure-related AE reported. At the twelve-month endpoint, there were a total of 27 device-related events in 21 of 130 (16.2%) patients and 21 procedure-related events in 19 of 130 patients (14.6%).

At the twelve-month endpoint, the most common device-related AEs in the SANS-UUI study were implant migrations (3.1% of patients), device stimulation issue (2.3%), implant fractures (1.5%), implant site pain (1.5%), medical device pain (painful stimulation due to high amplitude stimulation or after a fall) (1.5%), and medical device site burn (WT placed directly on skin) (1.5%). No other device-related AE occurred more than once (<0.8% of patients). There were no infections at the site of the implant.

At 12 months, there were 2 device fractures, 5 device migrations in 4 patients, 5 revisions, and 21 device explants. The majority of the migrations occurred within the first month of implant, and the fractures occurred on Day 26 and Day 63. However, one additional device fracture was seen after the 12-month data lock and was attributed to chiropractic manipulation.

8 MRI Safety Information

Non-clinical testing has demonstrated that the Neuspera SNM System neurostimulator is MR Conditional. The neurostimulator does **not** need to be programmed to a special mode to undergo an MRI.

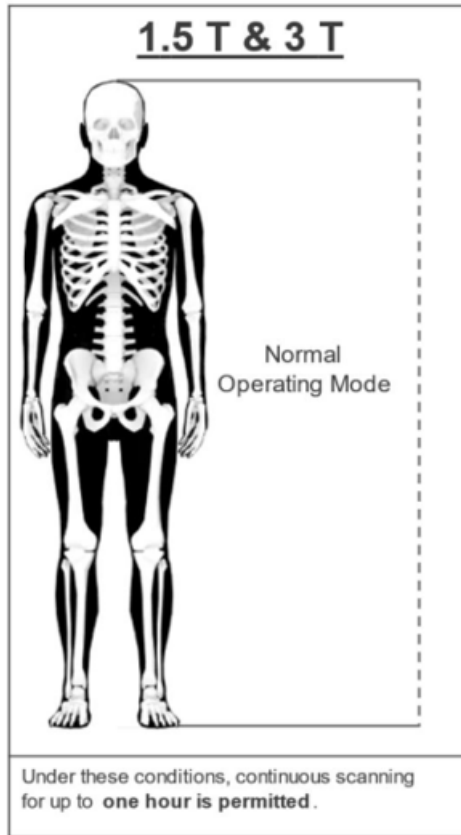
Remove all external components before scanning. The clinician and patient programmers, and accessory components including the intraoperative test kit, intraoperative external stimulator, guidewires, foramen needles, pre-dilators, delivery assembly and Wireless Transmitter have not been evaluated for safety in MRI and should be considered to be MR Unsafe. Do not bring them into the MR scanner room. If information about a specific parameter is not included, there are no conditions associated with that parameter.

A patient 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	1.5T or 3T

Scanner Parameters	Parameter Set
Strength (B0)	
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



9 Electromagnetic Interference (EMI) Precautions

Electromagnetic interference is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with neurostimulator function. Neurostimulators include features that provide protection from electromagnetic interference.

Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. However, sources of strong electromagnetic interference can result in operational

changes to the system causing the neurostimulator to not turn on or off as expected. Removing the source of external interference or moving away from interference source should stop unwanted stimulus.

■ **NOTE:** The neurostimulator can always be turned off by removing the Wireless Transmitter.

9.1 EMC-Related Precautions

- The Wireless Transmitter should not be worn by the patient or be anywhere near the implanted neurostimulator while the patient is undergoing any electromagnetic medical investigation or treatment.
- Diathermy (shortwave, microwave, or therapeutic ultrasound), radiofrequency ablation, and therapeutic ionizing radiation should not be used in the vicinity of the neurostimulator because these procedures have not been evaluated.
- Therapeutic ultrasound should not be used in the area of the neurostimulator as the device can inadvertently concentrate the ultrasound field and cause harm.
- Therapeutic ionizing radiation (e.g., radiation therapy for pelvic malignancy) can damage the electrical components of the neurostimulator and any damage may not be immediately detectable.
- The neurostimulator has not been evaluated for compatibility with other active implantable medical devices such as neurostimulators, drug pumps, pacemakers, or internal defibrillators. Do not use the System with an active implantable device.
- The neurostimulator has not been evaluated for compatibility with cardiac defibrillation. Check the performance of the neurostimulator after defibrillation.

9.2 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.

9.3 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.

10 Storage Conditions

Store in standard, controlled clinical storage.

Keep away from sunlight. Keep dry.

Storage temperature	-10°C to 55°C
Humidity	15% to 93%

11 Additional Supplies

Recommended tools (**IMPORTANT:** Consult tool accompanying documentation for sterilization methods)

- Basic surgical instruments (forceps, scalpels, Adsons tissue forceps etc.)
- C-Arm Fluoroscopy

Additional Neuspere Products:

- Neuspere Wireless Transmitter, non-sterile
- External Procedure Kit

- External Stimulator, non-sterile
- Intraoperative Ground Pad, non-sterile
- Intraoperative Cable, sterile
- Clinician Programmer, non-sterile

Do not detach or disassemble devices or use accessories not described in this instruction manual. The system may not function according to specifications under such conditions.

12 Resterilization

The components SHOULD NOT be resterilized. Before shipment, the kit is sterilized by ethylene oxide (EO).

13 Use Environments

Neuspera procedures will occur in hospitals, surgery centers, and clinics.

14 Patient Selection

Patients should be appropriate candidates for therapy evaluation and for potential surgical implant of an SNM system. Patients are contraindicated for therapy evaluation if their sacral depth measured from skin to the S3 foramen is greater than 10 cm as confirmed by imaging and they are unable to properly operate the Trial System.

The Trial System is intended to be used continuously during the stimulation trial. If the patient experiences a 50% reduction in urinary urge incontinence symptoms after the trial stimulation, they may proceed to receive a permanent system.

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

The safety and effectiveness of using the Neuspera System have not been established in the following:

- Patients with BMI > 40,
- Pregnant women,
- Pediatric patients,
- Bilateral stimulation with the permanent Neuspera SNM System (bilateral stimulation may be used with Trial System),
- Patients with neurologic cause of OAB such as multiple sclerosis, diabetes, or Parkinson's disease.

15 Implantation Procedure

IMPORTANT:

- **Ensure that x-ray imaging according to the Neuspera Radiographic Imaging Guidance is conducted and that sacral depth assessment is conducted and approved by Neuspera prior to the implantation procedure.**
 - **NOTE: If the sacral depth is too great, the Neuspera SNM System should not be used as the implant may not be able to be powered and may require an explant. For these patients, a different SNM device should be selected.**
- **A Neuspera Field Clinical Engineer (FCE) is required to be present at each implantation procedure. Please contact your local sales representative or call (888) 846-8332 or email Physicianhelp@neuspera.com to ensure an FCE will be present at the procedure.**
- **Have spare devices and tools for procedure.**

15.1 Preparation for the Procedure

1. Complete required training prior to procedure initiation.
2. Inspect the outer pouch for signs that it has been damaged, or the sterile seal has been broken. If there are signs of damage or the sterile seal is broken, retain for collection by Neuspera and replace with a new kit.
3. After opening the pouch, transfer the tray to a sterile field using sterile technique. Once removed from the pouch, the tray and its contents should remain in the sterile field.
4. Open the tray of the implant kit. Inspect the tools and neurostimulator for signs of damage. Do not use if damaged; retain for collection by Neuspera and replace with a new kit.

■ **NOTE:** The neurostimulator unique serial number can be found engraved on the metal cylinder of the proximal neurostimulator body and on the package labels. The serial number is a six-character hexadecimal code which is read from left to right.

IMPORTANT: Do not proceed with procedure if any implant tool is missing.

15.2 Preparation for the Patient

1. Obtain patient consent.
2. Place the patient in the prone position (see Figure 2).

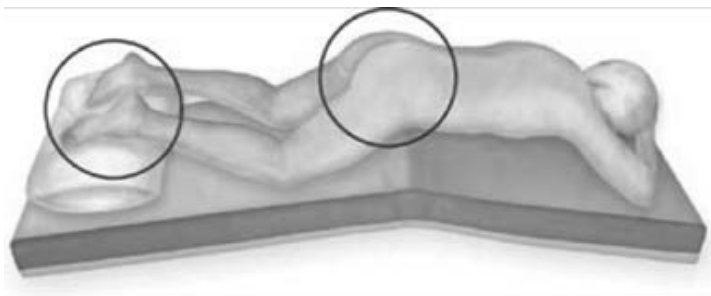


Figure 2. Patient positioning for implantation procedure

3. Administer local anesthesia, intravenous conscious sedation, or general anesthesia, as indicated for the patient.
4. Prepare the patient from the lower back to the bottom of the buttocks for sterile surgery.
5. Drape to allow observation of the buttocks/intergluteal fold and soles of the feet to confirm motor responses to stimulation.

15.3 Foramen Localization and S3 Foramen Mapping

1. Use fluoroscopy (A/P) to provide mapping of the S3 sacral region to allow for location of the sacral foramina and their medial edges (see Figure 3).

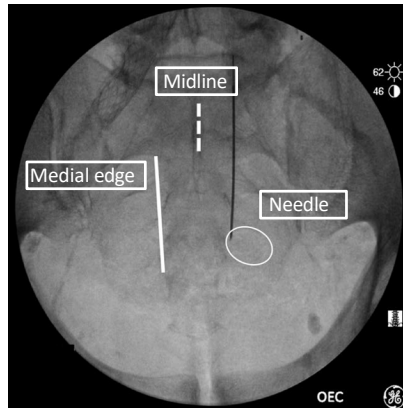


Figure 3. Mapping of S3 region

15.4 Needle Insertion and Motor Response Testing

1. Insert the foramen needle at the angle of the fusion plane between the third and fourth sacral segments, directed towards the upper medial margin of the S3 sacral foramen (see Figure 4). If necessary, adjust positioning by removing the needle and reinserting.

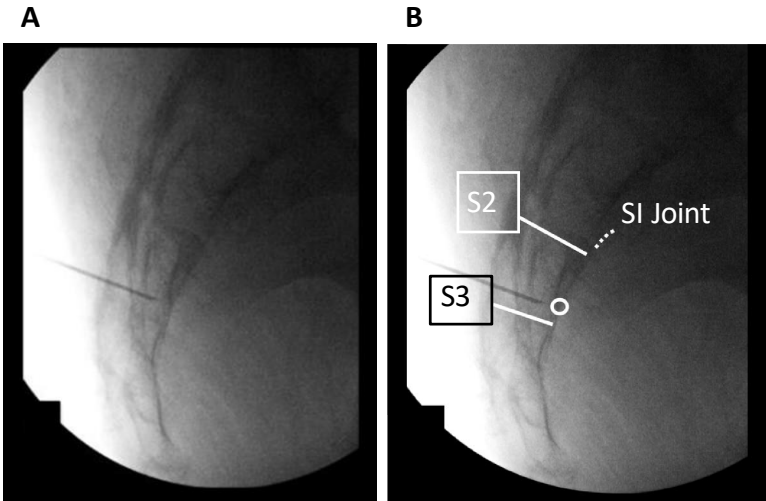


Figure 4. Lateral view of Foramen needle insertion A) needle parallels the angle of the fusion plane B) sacral bone seams/ fusion planes highlighted

2. Using fluoroscopy, ensure the foramen needle is inserted into the upper-medial aspect of foramen (see Figure 5).

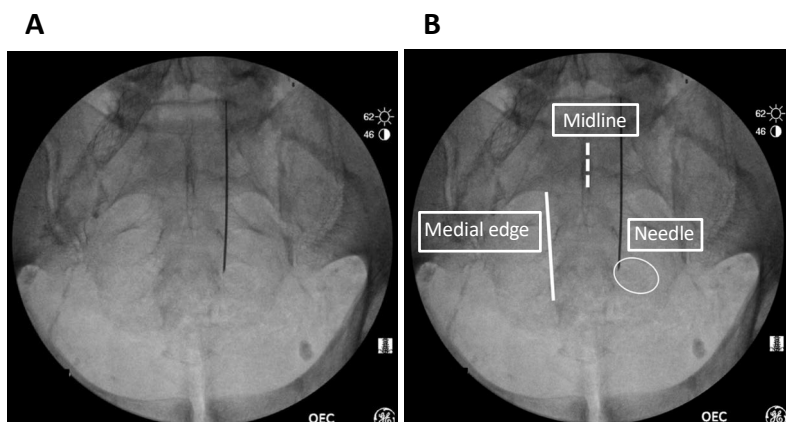


Figure 5. A/P view of Foramen needle insertion A) needle inserted into upper-medial aspect of foramen B) upper-medial aspect of foramen highlighted

3. Using A/P and lateral fluoroscopy views, confirm the location, orientation, and depth of the needle and, if necessary, adjust positioning by removing the needle and reinserting.
4. Outside the sterile field, after removing the pin cover, insert the Intraoperative cable pin (sterile) into white connector of the External Stimulator (non-sterile).
 - a. Connect a ground electrode to the External Stimulator.
 - b. Place the ground pad and External Stimulator on a non-hair bearing area of the skin (non-sterile).
 - c. Attach the j-hook of the intraoperative cable to the area of the needle just below the hub (in the sterile field).
 - d. Outside the sterile field, insert the Intraoperative cable pin (sterile) into white connector of the External Stimulator (non-sterile).

IMPORTANT: Ensure all cable connections are secure.

5. Stimulate at the anterior margin of the sacrum with standard settings at amplitudes ranging between 0-4.8V using the External Stimulator. Control the timing of the stimulation by touching the j-hook of the Intraoperative Cable to the dark area of the foramen needle. While observing for motor responses (bellows response and great toe/toe flexion), find the stimulation threshold. Aim for an opening threshold of less than 2.0 Volts. If the threshold is above 2.0 Volts, adjust position of foramen needle medially and or superiorly to minimize the stimulation threshold.
6. If motor responses are not observed using the S3 foramen, repeat the needle insertion procedure starting at step 1 using either the contralateral side or either of the S4 foramina. If no motor responses are observed in the S3 or S4 foramen, do not proceed with the implantation.
7. Remove the j-hook and Intraoperative Cable.

15.5 Sheath Delivery

1. Remove the stylet from the needle.
2. Insert the guidewire through the needle until the appropriate depth marker on the guidewire aligns with the top of the needle hub.
3. Withdraw the foramen needle over the guidewire while holding the guidewire stable.
4. Make a stab incision along one side of the guidewire.
5. **Optional:** Insert the pre-dilator over the guidewire and advance the pre-dilator until the tip of the pre-dilator is at the anterior edge of the sacral canal. If using a lateral

fluoroscopy view, ensure pre-dilator does not pass beyond the anterior sacrum edge (see Figure 6). Remove the pre-dilator while keeping the guidewire stable.

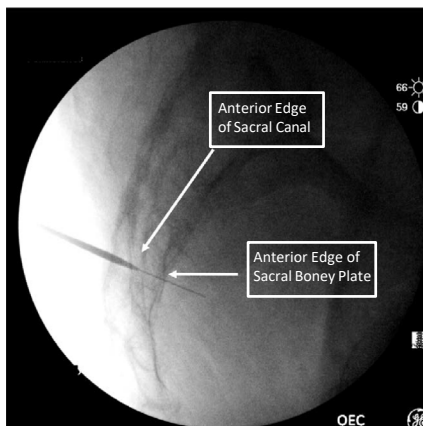


Figure 6. Ensure Pre-dilator is advanced to the anterior edge of the foramen.

6. Insert the 7F dilator/sheath assembly over the guidewire and advance the assembly until the tip of the assembly is at the anterior edge of the sacral canal (see Figure 7).

IMPORTANT: If the dilator/sheath assembly cannot easily pass through the sacral foramen, readjust or use the contralateral side foramen.

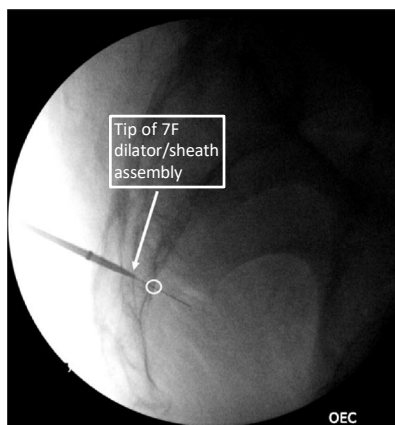


Figure 7. Move the tip of the 7F dilator/sheath assembly to the anterior edge of the sacral canal.

7. Remove the guidewire while leaving the dilator and sheath in position.
8. Using fluoroscopy (lateral view), confirm the tip of the 7F dilator/sheath assembly is at the anterior edge of the sacral canal.
9. Remove the dilator while leaving the sheath in position.

15.6 Device Implantation

IMPORTANT: Following initial deployment, do not attempt to place or reposition the neurostimulator after fully deploying more than three times (i.e. no more than two removal and reimplant attempts). Use a new kit if more attempts are required.

1. Pointing the tip of the neurostimulator posterolateral towards the ipsilateral side, insert the neurostimulator/push rod assembly into the sheath. Using fluoroscopy, while holding the sheath in place, advance the assembly until the black marker on the push rod reaches the top of the sheath hub.

2. Using fluoroscopy (Lateral view), ensure Electrode #3 is completely outside of the sheath and below the anterior edge of the sacrum.
3. Using fluoroscopy (Lateral view), confirm that the neurostimulator is in the proper position in the sacrum and angled inferiorly. The demarcation between the IPG and antenna should be placed at the posterior bone edge in a properly aligned lateral fluoroscopic view (see Figure 8A).

IMPORTANT: Confirmation of the correct implant placement is important to reduce risk of device migration.

4. Using fluoroscopy (A/P view), confirm that the neurostimulator is angled with the tip pointing mediolaterally with appropriate appearance of spacing between contacts (see Figure 8B).

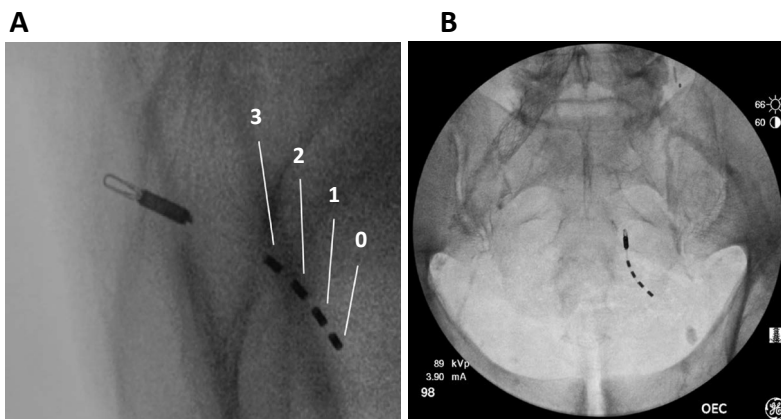


Figure 8. Fluoroscopic images showing correct position and orientation of the neurostimulator. A) In the lateral view, the demarcation between the IPG and antenna should be placed at the posterior bone edge. The electrode array parallels the fusion plane between the third and fourth sacral segments, enter above the hillock, and curves caudally. Ensure Electrode #3 is completely outside of the sheath at or below the anterior edge of the sacrum. Distal electrodes typically appear to be more closely spaced together than proximal electrodes. B) In the A/P view, the electrode array starts close to the medial edge of the foramen and curves out mediolaterally. Proximal electrodes typically appear to be spaced more closely together than distal electrodes.

5. Save the image after verifying the following:

- The posterior edge of the sacrum is within the section labeled “sacrum posterior alignment zone” and the anterior edge of the sacrum is within the section labeled “sacrum anterior alignment zone.” See Figure 9 for a diagram view and Figure 10 for fluoroscopy view.
- Required depth of device placement:
 1. The junction between IPG can and antenna (A) is at or just posterior to the posterior edge of the sacrum on lateral x-ray view. This ensures the proximal tines are seated in the multifidus muscle or fascia.

2. Contact number 3 (B) should be at or near the anterior edge of the sacrum. This is typically the case when the can is positioned as above.
3. If the sacrum is unusually thick or thin, it is more important to optimize the position of the can than the position of contact 3. This allows proper seating of the tines and still allows for selection from electrode pairs for therapy.

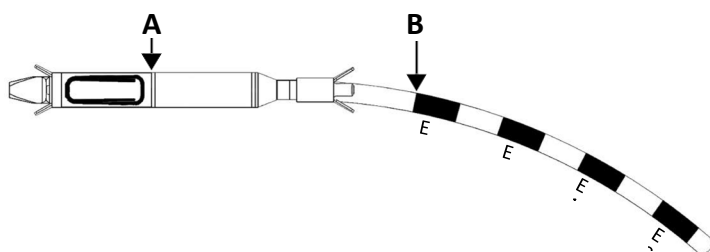


Figure 9. The most proximal end of the implant (visible through fluoroscopy), marked by point A, should be at the posterior edge of the sacrum. The proximal end of Electrode #3, marked by point B, needs to be at the anterior edge of the sacrum.

NOTE: Implant features can be used to estimate anatomical distances in the lateral fluoroscopy view.

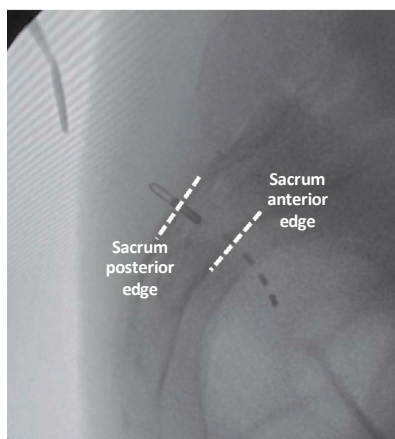


Figure 10. The most proximal end of the implant visible through fluoroscopy must be at the posterior edge of the sacrum. The proximal end of Electrode #3 needs to be at the anterior edge of the sacrum.

6. If after initial introduction the device position does not meet the verification criteria in step 2 and 3, adjust as necessary until all criteria are met.

15.7 Stimulation Protocol Prior to Full Deployment

IMPORTANT: Refer to the Clinician Manual for instructions on how to use the Clinician Programmer. Prior to the implantation procedure, using the Clinician Programmer (non-sterile), assign at least one Wireless Transmitter to the patient's neurostimulator.

1. Using the Clinician Programmer outside the sterile field, adjust the electrode configuration and stimulation parameters as necessary.
 - a. The default vector configuration is:
 - Electrode 0 (most distal) = anode (positive)
 - Electrode 1 = off
 - Electrode 2 = off
 - Electrode 3 (most proximal) = cathode (negative)

- b. The default stimulation settings are:
 - 0.2 V amplitude
 - 210 microseconds pulse width
 - 14 Hz frequency
2. Use a sterile drape to separate the Wireless Transmitter 1 to 10 mm from the skin surface. Fold the sterile drape if necessary. Place the Wireless Transmitter in a sterile sleeve and position it on top of a sterile drape placed over the implant site.
3. To initiate stimulation, activate the Wireless Transmitter using the Clinician Programmer.

Table 19: Stimulation electrode pair testing for observed motor responses

Test	Electrode				Threshold
	0	1	2	3	
1	(–)	(+)	off	off	<i>Record</i>
2	off	(–)	(+)	off	<i>Record</i>
3	off	off	(–)	(+)	<i>Record</i>

Table 20: Neuspera Sacral Nerve Stimulator specifications

Amplitude	0–1V	100 mV increments		
	1.2–4.8V	200 mV increments		
Frequency	5–130 Hz			
Pulse Width	30–960 Hz			
Cycling (Default off)	min	off	max	off
	min	on	max	on

4. When the System is stimulating, document all physiological responses to the stimulation in the patient record, including:
 - Bellows
 - Flexion of the great toe/toes
 - If the patient is under conscious or local sedation, ask the patient for a sensory response confirmation
5. If no motor responses are observed:
 - a. Increase the stimulation amplitude through the Clinician Programmer up to 4.8 V and/or
 - b. Slowly move (rotate) the Wireless Transmitter around the implantation site
6. Repeat Stimulation Protocol section steps to check functionality of all electrode pairs.
7. If repositioning of the neurostimulator is needed to achieve a motor response threshold of less than 2.0 Volts, depending on the position of the neurostimulator, the following actions may be taken:
 - a. Pull the pushrod/device back into the introducer sheath so that the electrode array is withdrawn past the radio-opaque marker.
 - b. Rotate the pushrod/device clockwise or counter clockwise to aim the curve up or down depending on the side of the implant.
 - c. After turning, re-introduce the assembly to the normal implant depth to re-align along the nerve target.
 - d. Repeat the stimulation protocol steps.
 - e. Repeat steps a through c if results are not optimal.

- f. Consider withdrawing introducer sheath and re-introducing after replacing foramen needle and testing at different angle, or go to the opposite side if still not getting satisfactory responses.

15.8 Device Deployment

1. Using fluoroscopy, steadily keeping the push rod in place with one hand, use the other hand to partially withdraw the sheath until it meets the handle of the push rod and cannot withdraw further. This confirms the deployment of the proximal tines.
2. Using fluoroscopy (lateral view), ensure that the neurostimulator has not moved. Adjust position, if necessary.
3. Unscrew and remove luer-lock cap from the push rod.
4. Unfurl the tethered suture from the push rod hub.
5. Remove the push rod over the tethered suture.
6. Using fluoroscopy (lateral view), ensure that the neurostimulator has not moved.
7. Slowly remove the sheath.
8. Use fluoroscopy to visualize the neurostimulator position. Using a radiopaque object (e.g., hemostat, dilator, etc.) on the skin above the neurostimulator as a reference marker, take anterior-posterior (A/P) and lateral images of the implanted neurostimulator. If neurostimulator is too deep, adjust position of neurostimulator by pulling on the tethered suture and save A/P and lateral image.
9. Repeat stimulation protocol steps in Section 9.7 to ensure that device remains in position. If other repositioning is required, remove the neurostimulator and reimplant.
10. To reload the neurostimulator onto the push rod for reimplantation:

- a. Straighten the suture by firmly pulling the suture between the thumb and index finger while holding the proximal end of the neurostimulator with the other hand.
- b. Insert the loose end of the suture into the distal end of the push rod. If it is difficult to insert, wet the suture with saline.
- c. Feed the suture through the push rod until the end of the suture exits the proximal end of the push rod.
- d. Pull the loose end of the suture taut while aligning the distal end of the neurostimulator with the prongs on the push rod (see Figure 11).

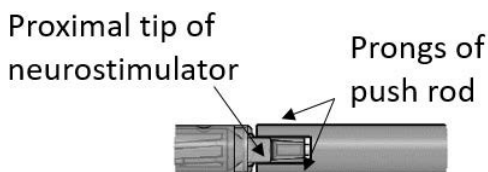


Figure 11. Neurostimulator aligned with prongs on the push rod

- e. Keeping the suture taut, wind the loose end of the suture 2-3 times around the proximal end of the push rod handle and secure using the luer lock.
11. Placing a radiopaque object (e.g., hemostat, dilator, etc.) on the skin at the shortest distance from the neurostimulator as a reference marker, take anterior-posterior (A/P) and lateral images of the implanted neurostimulator and save for the patient record.

• ***Suture Trimming and Incision Site Closure***

12. Holding tethered suture, push down on implant site and cut suture flush with the skin ensuring a sufficient length of suture is available should location and retrieval of the neurostimulator be necessary. Allow suture to retract under dermis when pressure is released (recommended to use Adsons tissue forceps to pull up skin around

incision site to ensure string is under skin).

13. Cover or close incision site with a suture or Dermabond®.
14. Save final lateral and A/P images of neurostimulator position for the patient record.

16 Neurostimulator Removal Procedure

1. Recommended tools (**IMPORTANT:** Consult tool accompanying documentation for sterilization methods):
 - Basic surgical instruments (forceps, scalpels, weitlaner retractor, Senn, etc.)
 - Fluoroscopy
2. Using a radiopaque object on the skin above the neurostimulator as a reference marker, take a lateral fluoroscopy image of the implanted neurostimulator and save for the patient record.
3. Make an approximate 1.5-2.5 cm long incision above the implant site and attempt to locate the tethered suture tail. If the tethered suture is found, pull on it in with gentle pressure in the same direction as implantation path.
 - a. If the neurostimulator cannot be completely removed using the tethered suture, dissect along suture.
 - b. If the neurostimulator cannot be completely removed using the tethered suture, dissect along suture until able to palpate to feel the top of the device. It can be helpful to insert a foramen needle or similar sized spinal needle into the foramen using fluoroscopy as in the initial steps to position the device. This can help guide dissection along the course of the needle to the implanted device to the level of the foramen.

- c. If the top of device cannot be felt, use fluoroscopy to guide dissection to locate the top of the device.
 4. Use forceps to grip the top of the neurostimulator and gently pull to remove.
 - **NOTE:** Pull the neurostimulator steadily without twisting or rolling.
 5. Take another prone x-ray or lateral fluoroscopy of the implantation site and save for the patient record.
 6. If the removed neurostimulator is being replaced, follow the steps in Section 9, “Implantation Procedure” and place the new neurostimulator in the contralateral foramen. Otherwise, close the wound.
 7. Save the removed neurostimulator and return to Neuspera.
-

17 Component Disposal

1. Follow local facility practices and policies for the return and disposal of tools as appropriate.
2. After completion of implantation procedures, return any neurostimulators that were not successfully implanted to Neuspera. To allow for device analysis, do not autoclave the devices or expose to ultrasonic cleaners.
3. After removing the neurostimulator (e.g., replacement, cessation of therapy, or post-mortem), return the removed neurostimulator, Wireless Transmitter(s), and Patient Controller to Neuspera. To allow for device analysis, do not attempt to clean or sterilize the devices.

CAUTION:

- Follow appropriate biohazard controls for all removed components or components coming into contact with bodily fluids. Contact Neuspera (see contact information on back page) to obtain appropriate packaging materials for all returns.
- Do not reuse any implantable device or implantable accessory after exposure to body tissues or fluids because the sterility and functionality of the component cannot be guaranteed.

18 Symbols and Glossary

18.1 Symbols

Symbol	Description
	Catalog number
	Batch code
	Serial number
	Quantity
	Sterilized using ethylene oxide
	Manufacturer
	Date of manufacture
	Use by date
	Consult instructions for use
	Do not use if package is damaged
	Do not re-use
	Do not re-sterilize
	Magnetic Resonance (MR) Conditional
	Magnetic Resonance (MR) Unsafe
	Temperature limit

Symbol	Description
	Humidity limitation
	Keep away from sunlight
	Keep dry

18.2 Glossary of Terms

Acronym	Term
SNS	Sacral Nerve Stimulation
WT	Wireless Transmitter
UUI	Urinary Urge Incontinence
MRI / MR	Magnetic Resonance Imaging / Magnetic Resonance
EM / EMI	Electromagnetic / Electromagnetic Interference
SAR	Specific Absorption Rate
REF	Reference
EO	Ethylene Oxide
A/P	Anterior / Posterior
cm	Centimeters
T	Tesla
G	Gauss
m	Meter
W	Watt
kg	Kilogram
°C	Celsius



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Neuspera Sacral Neuromodulation System

Clinician Manual

R_x only

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

Symbol	Description
	Catalog number
	Batch code
	Serial number
	Quantity
	Wireless transmitter identification number
	Sterilized using ethylene oxide
	Manufacturer
	Date of manufacture
	Use before date
	Refer to instruction manual
	Consult Instructions for Use
	Do not use if package is damaged
	Do not re-use
	Do not re-sterilize
	Magnetic Resonance (MR) Conditional
	Magnetic Resonance (MR) Unsafe
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Keep away from sunlight
	Keep dry

Symbol	Description
	Protected from touch by fingers and objects greater than 12 millimeters. Protected from low pressure water jets from any direction)
	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
	Machine wash warm
	Non chlorine bleach
	Tumble dry low
	Iron low heat

Glossary of Terms	
EM / EMI	electromagnetic / electromagnetic interference
IT	information technology
mA / μ A	milliamperes / microamperes
MR / MRI	magnetic resonance / magnetic resonance imaging
UUI	urinary urge incontinence
RF / RFID	radiofrequency / radiofrequency identification
SAR	specific absorption rate (measure of wireless power absorbed by the body)
SNS	sacral nerve stimulation
USB	universal serial bus
V	volts
WT	wireless transmitter

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1. INTRODUCTION

The Neuspera Sacral Neuromodulation System (SNM) uses mid-field powering to power an implanted Neurostimulator using an externally worn device (Wireless Transmitter).

2. SYSTEM DESCRIPTION AND OPERATING PRINCIPLE

The Neuspera SNM System consists of an implantable neurostimulator combining a receiver antenna, hermetically sealed electronic package, and timed stimulation electrode array with four programmable electrodes. The hermetically sealed electronic package consists of an integrated electronic circuit with a custom application specific integrated circuit and flex circuit interconnect. This package harvests the received energy, manages power and communication, and generates stimulation. The electrode array delivers stimulation to the sacral nerve.

There is no implantable battery in the SNM System. The implanted neurostimulator is powered by an externally worn WT which contains a rechargeable battery. Power is delivered to the implanted neurostimulator using Neuspera's proprietary mid-field powering technology. The WT is worn over the patient's sacrum, directly over the implanted neurostimulator, and held in position by a custom undergarment. The WT is controlled by custom software applications (referred to as the Clinician Programmer and the Patient Controller) running on off-the-shelf portable hardware. The rechargeable battery of the WT is charged by an off-the-shelf charging pad.

The Implantable Sacral Nerve Stimulation Kit (implant tools) are used to introduce and implant the neurostimulator. Additionally, the Intraoperative Cable and External Stimulator are used to identify the location of the sacral nerve by observing motor responses (bellows response and toe flexion) to stimulation.

Prior to being permanently implanted with the device, the patient will first undergo an intraoperative test stimulation of the sacral nerve using a foramen needle and an external stimulator. After the nerve is located and if an acceptable response is elicited, the patient next proceeds to a period of at-home trial stimulation for up to seven days. The trial period is used to evaluate the effects of the therapy on the patient's symptoms (via a bladder diary) and to assess possible side effects. This information is used to determine if the patient is a candidate for long-term treatment with the permanent Neuspera SNM System.

2.1. Device Description

The Neuspera SNM System consists of the following components (names in parentheses are trade names):

- Neuspera Sacral Nerve Stimulator Implant Kit, including the Implantable Neurostimulator ("Implant Kit")
- External Components
- Wireless Transmitter and Accessories (Charging Pad and Magnet)
- Clinician Programmer
- Patient Controller
- Undergarment
- Trial System
- Trial System Kit ("Trial Lead Kit")
- Trial Lead Kit ("Extra Trial Lead")

- Procedural Accessories Kit
- External Procedural Kit (“External Nerve Stimulator Kit”)

The Implantable Neurostimulator is an implantable neurostimulator with four programmable electrodes. The programmable electrodes deliver stimulation to the sacral nerve. See **Figure 1**.

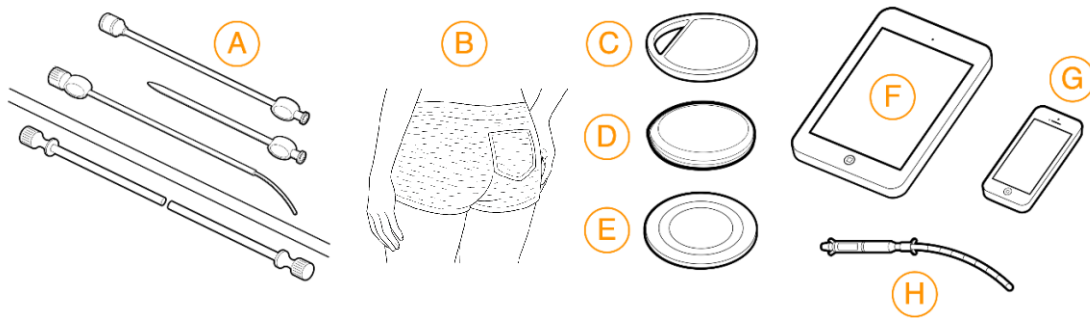


Figure 1. Neuspera SNM System

A. Implantable Sacral Nerve Stimulator Kit (Including Implantable Neurostimulator), B. Undergarment, C. Magnet, D. Wireless Transmitter, E. Charging Pad, F. Clinician Programmer, G. Patient controller, and H. Implantable Neurostimulator

2.1.1. Implantable Neurostimulator

The neurostimulator (see **Figure 2**) delivers pulses of energy to the sacral nerve that helps control the bladder. The distal portion is pre-formed with a curvature and contains four electrodes for stimulation. The proximal end has an encapsulated antenna to receive the signal from the Wireless Transmitter. Circuitry in a hermetic package receives communication and rectifies the signal from the Wireless Transmitter to transiently store energy and generates programmable electrical pulses to the stimulation electrodes. Radial tines are designed to maintain the position of the implant after implantation. Specifications of the neurostimulator are provided in **Table 1** and **Table 2**.



Figure 2. Neuspera Implantable Neurostimulator

Table 1. Neurostimulator Dimensions and Materials

Dimensions	
Electrode size	3 mm
Electrode spacing	3 mm
Neurostimulator length (excluding tether)	44 mm
Neurostimulator diameter	2.3 mm
Materials	
Electrodes, Feedthrough Flanges, Proximal Circuitry Housing	Platinum/Iridium 90/10
Distal Nose, Distal Electrode Array Body, and Tines	Thermoplastic polyurethane
Adhesive connecting device segments	Epoxy
Push Rod Keying feature	Polyetheretherketone (PEEK)
Tethered Suture	Expanded Polytetrafluoroethylene

Table 2. Neurostimulator Specifications

Stimulation Parameter	Neurostimulator Specification
Amplitude	0.2-4.8 V
Pulse width duration	105-945 μ s
Pulse frequency	5-100 Hz
Mode	Continuous or Cycling

2.1.2. External Components

Wireless Transmitter (WT) and Accessories (Charging Pad and Magnet)

The Wireless Transmitter (WT) is an externally worn device used to power and communicate to the neurostimulator and is programmed and controlled using the Clinician Programmer and Patient Controller. It contains a rechargeable battery that is recharged on the charging pad. Specifications of the Wireless Transmitter are provided in **Table 3**. Stimulation of the neurostimulator only occurs while the WT is placed over the implant site.

The Charging Pad is used to recharge the Wireless Transmitter, and the Magnet is used to reset the Wireless Transmitter and to turn the Wireless Transmitter off to conserve battery power.

Table 3. Wireless Transmitter Specifications

Feature	Wireless Transmitter Specification
Battery capacity	≥2000 mAh
Battery capacity (therapy time)	≥2 hours (will vary with RF power control settings)
Time for full recharge	≤5 hours
Frequency range (powering)	902-928 (ISM compliant band)
Frequency range (Bluetooth)	2.4-2.5GHz

Clinician Programmer (CP)

The Clinician Programmer is used by the clinician to manage the Wireless Transmitter associated with the patient's neurostimulator and program a patient's stimulation therapy.

Patient Controller (PC)

The Patient Controller is used by the patient to turn the Wireless Transmitter on/off, adjust stimulation amplitude, and select pre-configured stimulation programs.

Undergarment

The Neuspera Undergarment is used to place and hold the Wireless Transmitter in the correct position for therapy. The specifically designed pocket will also pad and insulate the Wireless Transmitter against the body. The Undergarment is intended to be worn under general clothing (i.e. pants, shirts, and jackets). It is also compatible with pads and diapers. The Undergarment is available in six sizes, from Extra-Small to XXX-Large in Men's Briefs or Women's Low-Rise Hipster designs.

2.1.3. Implantable Sacral Nerve Stimulation (SNS) Tool Kit

The Implantable SNS Tool Kit contains the following tools needed to introduce and implant the neurostimulator.

- The foramen needle is used to locate the foramen, test stimulate the implantation location using the Intraoperative Cable and Ground Pad, and External Stimulator, and introduce the guidewire.
- The pre-dilator provides initial dilation of the neurostimulator introduction pathway.
- The dilator/sheath assembly introduces the sheath to the correct location in the foramen and the sheath introduces the neurostimulator.
- The guidewire is used to place the pre-dilator and dilator/introducer sheath assembly.
- The push rod is a tool used to place the neurostimulator correctly in the foramen through the sheath. The neurostimulator is pre-loaded on the push rod.

2.1.4. Trial System

The Trial System is used for trial stimulation to determine efficacy before recommendation for a permanent implant and to test the implant location prior to deployment of the Implantable Neurostimulator. See **Figure 3** for Trial System components.

The Trial System consists of the following kits:

- Trial Lead Kit
- Extra Trial Lead
- Procedural Accessories Kit
- External Nerve Stimulator Kit

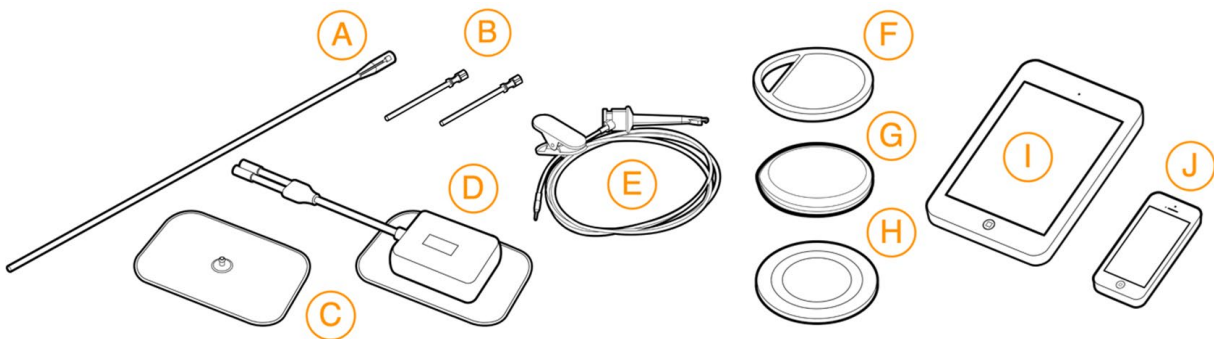


Figure 3. Neuspera Trial System Components

A. Trial Lead with Stylet; B. 3.5" Foramen Needle (protective cap not shown); C. Intraoperative Ground Pad; D. External Stimulator with Ground Pad; E. Intraoperative Cable; F. Wireless Transmitter Magnet; G. Wireless Transmitter; H. Charging Pad; I. Clinician Programmer; J. Patient Controller. Procedural Accessories not shown.

Trial Lead with Stylet

The Trial Lead is a temporary 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 using a percutaneous procedure. The Trial Lead is 34 cm long and has a diameter of 0.84 mm. The contact is 7.4 mm in length. The Trial Lead is introduced through the sacral foramina to allow the electrode at its tip to stimulate the sacral nerve root; the remainder of the Trial Lead exits the skin to be connected to the External Stimulator.

External Stimulator with Trial Ground Pad

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 Trial System is intended to be used continuously during the stimulation trial. The stimulation parameter ranges for the External Stimulator are listed in **Table 4**. The stimulation parameters, ranges, and waveform from the External Stimulator are identical to the output of the Neuspera implantable neurostimulator.

Table 4. External Stimulator Specifications

Stimulation Parameter	External Stimulator Specification
Amplitude	0.2 – 4.8 V
Pulse width duration	105-945 μ s
Pulse frequency	5-100 Hz
Mode	Continuous or Cycling

Do not detach or disassemble devices, or use accessories not described in this manual. The system may not function according to specification under these conditions.

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

No technical maintenance is required on any of the Neuspera System components.

2.2. Intended Use

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

3. PRESCRIPTION AND SAFETY INFORMATION

The Neuspera SNM System is for use with a prescription only. The system should only be implanted by physicians trained in placement of sacral neuromodulation devices.

3.1. Contraindications

- Patients with sacral depth measured from skin to the S3 foramen greater than 10 cm as confirmed by imaging.
- Patients who have not demonstrated an appropriate response to test stimulation
- Patients who are unable to operate the neurostimulator
- Men who have Benign Prostatic Hyperplasia (BPH) or patients with other lower urinary tract obstructions that leads to significant obstructive symptoms or pathology.

After implantation of the Neurostimulator, the following contradictions apply:

- Electrical treatments where the conducted current is induced into the body from an external source in the area of the Neurostimulator (this may permanently damage the Neurostimulator).
- Medical treatments or procedures utilizing effects caused by electric fields (such as diathermy) unless the treatment or procedure is identified within as acceptable (such as MRI).

3.2. Warnings

Do not detach or disassemble devices, or use accessories not described in this manual. The system may not function according to specification under these conditions.

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

Implant fracture or migration may occur. Patients should be monitored for potential fracture or migrations if they have any loss of stimulation.

Inform patients of the following warnings:

- Wearing the Wireless Transmitter against your skin may result in discomfort, irritation, or a burn.

- Do not place the Undergarment in direct contact with compromised skin such as open or healing wounds. Follow the instructions provided by your clinician for post operative wound care after implantation of the Neuspere neurostimulator.
- Do not use the Wireless Transmitter in situations where the temperature is very hot (above 35°C or 95°F) or in conditions where there is limited air circulation (such as under a blanket, heavy clothing, or in a heavily padded chair). Doing so could result in the Wireless Transmitter overheating. Burns or other injury could result.
- Do not use the Wireless Transmitter if you are unable to feel that the device is getting too hot, such as while sleeping. Burns or other injuries could result.

Electromagnetic Interference (EMI) from various sources may damage the device, interfere with device operation, or cause harm to the patient. Please consider the following:

- Defibrillation or Cardioversion
 - When a patient is in ventricular or atrial fibrillation, the first consideration is patient survival. External defibrillation or cardioversion can damage the Neurostimulator and cause induced currents in the Neurostimulator that can injure the patient. Minimize the current flowing through the Neurostimulator by following these guidelines:
 - Position defibrillation paddles as far from the Neurostimulator as possible.
 - Position defibrillation paddles perpendicular to the Neurostimulator.
 - Use the lowest clinically appropriate energy (joules) output (watt seconds).
 - After defibrillation, confirm the Neurostimulator is functioning as expected.
- Electrocautery
 - If electrocautery is used near an implantable device or contacts a device or insertion-needle, the following effects may occur:
 - The tissue surrounding the device may be damaged.
 - The Neurostimulator may be damaged, or stimulation may be temporarily suppressed or increased.
 - When electrocautery is necessary, follow these precautions:
 - Before using electrocautery, remove the Wireless Transmitter.
 - Bipolar cautery is recommended.
 - Keep at least 2 inches from the implant
 - If unipolar cautery is necessary, follow these guidelines:
 - Use only a low-voltage mode.
 - Use the lowest possible power setting.
 - Keep the current path (ground plate) as far from the Neurostimulator as possible.
 - Keep at least 2 inches from the implant
 - Do not use full-length operating room table grounding pads.
 - After using electrocautery, confirm that the Neurostimulator is functioning as intended.
- High-output ultrasonics or lithotripsy – Use of high-output ultrasonic devices, such as electrohydraulic lithotripters, is not recommended for patients who have an implanted Neurostimulator. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the Neurostimulator circuitry. If lithotripsy must be used, remove the Wireless Transmitter and do not focus the beam within 15 cm (6 in) of the Neurostimulator.
- Radiofrequency (RF) or microwave ablation – Safety has not been established for RF or microwave ablation in patients who have an implanted Neurostimulator. Induced electrical currents may cause heating of the Neurostimulator resulting in tissue damage.

- Effects of monitoring devices – When using diagnostic monitoring devices such as an electrocardiogram (ECG), Holter Monitor, or electroencephalogram (EEG), have the patient remove the Wireless Transmitter as pulses from the Neurostimulator may be detected as an electrical signal.

- Theft detectors and security screening devices

Note: Some theft detectors and screening devices may not be visible.

- Theft detectors found in retail stores, public libraries, etc., and security screening devices found in airports, government buildings, etc., may occasionally cause a momentary change in stimulation. When passing through these devices while wearing the Wireless Transmitter, some patients may perceive intermittent stimulation as therapy is switching on and off. It is also possible that patients, especially those that have low stimulation levels, may feel a momentary change in stimulation when they pass through these devices.
- When approaching these devices, patients should do the following:
 - If possible, instruct patients to request to bypass these devices. Security personnel may use a handheld security wand but patients should ask the security personnel not to hold the security wand over the Neurostimulator any longer than is absolutely necessary. Patients may wish to ask for another form of personal search.
 - If patients must pass through the theft detector or security screening device, they should turn off or remove their Wireless Transmitter.
 - If two security gates are present, they should walk through the middle at a normal pace, keeping as far from each gate as possible.
 - If one gate is present, they should walk as far from it as possible.
 - Proceed through the security device at a normal pace. Patients should not lean or linger on the screening device.
 - After patients pass through the security device, they should re-enable therapy.

3.3. Precautions

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

- Prior to use, clinicians should be trained on the implantation procedure and use of the Neuspera SNM System.
 - Implanting clinicians should be trained on sacral nerve stimulation (SNS), the implantation procedure, and use of the Neuspera System. A formal training program, including both a didactic session and a hands-on training lab, will be provided for the Neuspera SNM System; clinicians will be required to pass a formal knowledge assessment prior to implanting the device.
 - A Neuspera Field Clinical Engineer (FCE) is required to be present at each implantation procedure. Please contact your local sales representative or call (888) 846-8332 or email Physicianhelp@neuspera.com to ensure an FCE will be present at the procedure.
 - Prescribing clinicians should be experienced in the diagnosis and treatment of lower urinary tract symptoms and should be trained on the use of the Neuspera SNM System.
- The Neuspera Sacral Nerve Stimulator Implant Kit and External Nerve Stimulator Kit are single use only. Reuse of these devices may result in patient harm including, but not limited to, systemic infection.
- The implantation procedure requires use of fluoroscopy, and it is recommended that the fluoroscope documentation be consulted for applicable warnings, contraindications, etc.

- Do not use the Wireless Transmitter, Patient Controller, charging pad, or charging cables if they are damaged. Using damaged devices and cables may result in fire, electrical shock, injury, or additional damage.
- Ensure the Wireless Transmitter is not punctured or damaged to prevent battery leakage.
- If rash or other adverse skin reactions occur, instruct the patient to stop using the device, and monitor the skin.
- The Wireless Transmitter should only be worn in the pocket of the Undergarment to prevent injury or skin irritation from a hot Wireless Transmitter. The Wireless Transmitter is not intended for direct skin contact.
- Instruct the patient to turn off stimulation or remove the Wireless Transmitter if it becomes uncomfortably hot.
- Instruct the patient to avoid taking substances that may impair your ability to feel the Wireless Transmitter getting too hot. This may increase the chance of being injured from the elevated Wireless Transmitter temperature.
- The Wireless Transmitter may heat up while charging. Instruct the patient to not wear the WT while it is charging. The Wireless Transmitter cannot stimulate while charging. If the WT needs to be charged, another WT may be worn in the Undergarment instead and used to activate the neurostimulator.
- External pressure used during some medical procedures may damage the Neurostimulator which may require surgery to replace the device. During x-ray procedures that require external compression around the implanted Neurostimulator, the x-ray equipment should be adjusted to limit the amount of pressure exerted on the Neurostimulator.
- Patients with broken or blistered skin or with poor circulation in the area of the Neurostimulator should not use the Neuspera SNM System unless skin is covered with a bandage or until the skin has healed. Use medical judgement to determine if patients with these conditions may be more susceptible to thermal injuries prior to applying the Wireless Transmitter.
- The Wireless Transmitter should be worn with the Undergarment to minimize misalignment and loss of therapy. The Undergarment keeps the Wireless Transmitter from becoming separated or misaligned from the implanted Neurostimulator. This ensures that the Wireless Transmitter sufficiently powers the Neurostimulator at the programmed therapy settings.
- The Wireless Transmitter, Patient Controller, and Clinician Programmer should not be brought into any room with an MR machine. Doing so could cause them to be drawn into the bore of the MRI and cause serious injury to the patient.
- Non-clinical testing has demonstrated that the Neurostimulator is MR Conditional; see MRI Safety Information Section.
- The safety and performance of the Neuspera SNM System has not been evaluated for use in the following:
 - Patients with BMI > 40,
 - Pregnant women,
 - Pediatric patients,
 - Bilateral stimulation with the permanent Neuspera SNM System (bilateral stimulation may be used with Trial System),

- Patients with neurologic cause of OAB such as 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 Neuspera System with an active implantable device.
- The Neuspera System has not been tested for compatibility with cardiac defibrillation.
- 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.

3.3.1. Patient Activities

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

- Patients should avoid sexual activity

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

- Patients should limit physical activities that may put stress on the Neurostimulator.
- Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause component fracture or dislodgement.

During the SANS-UII Phase II clinical study, some patients had devices that migrated due to not limiting physical activities after implant; these migrations generally occurred within the first six weeks following the implant procedure.

Component fracture or migration may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Examples of such activities include gymnastics, mountain biking, and other sports or equipment that involve the movements described above.

After being implanted with the Neuspera SNM System:

- Strenuous physical activity may cause Neurostimulator fracture or migration which may result in loss of stimulation, intermittent stimulation, or pain at the Neurostimulator site.
- Avoid diving below 10 meters (33 feet) of water or entering hyperbaric chambers above 200kPa.
- Postural changes, and other activities may result in the patient perceiving an increase in stimulation which may be uncomfortable. Some patients have described this as a jolting or shocking sensation.
- Patients should consider movements involved in any planned activity and take precaution to avoid putting undue stress on the Neurostimulator. For example, in activities such as skydiving, when the parachute opens, there can be a sudden jerking motion that occurs. This may cause a Neurostimulator migration or fracture. A surgical procedure may be required to reposition or replace the Neurostimulator. Ask your patients to inform you about the activities in which they participate and inform them of any additional activity restrictions.

While stimulation is occurring:

- Patients should be instructed to not wear the Wireless Transmitter to deliver therapy during activities that could be unsafe for themselves or others (e.g., driving or the use of dangerous equipment) if they were to receive an unexpected jolt or shock.
- Patient should avoid taking substances that may impair their ability to feel the Wireless Transmitter getting too warm and to not sleep or use heavy clothing or blankets while using the

Wireless Transmitter. This may increase the chance of being injured from the elevated Wireless Transmitter temperature.

- Patients should not wear the Wireless Transmitter during charging. The Wireless Transmitter may heat up while charging. The Wireless Transmitter cannot stimulate while charging. If the WT needs to be charged, another WT may be worn in the Undergarment instead and used to activate the Neurostimulator.
- Metal surfaces (e.g., wall, chair back) against the Wireless Transmitter may temporarily interrupt therapy (stimulation).
- It is normal for the Wireless Transmitter to get warm during therapy. If the WT becomes uncomfortably hot, the patient should turn it off or remove it.

3.3.2. Component Manipulation

After being implanted with the Neuspera SNM System, patients should refrain from receiving any form of spinal or pelvic manipulation in the area of the Neurostimulator by chiropractors as this may damage the Neurostimulator. This may result in Neurostimulator fracture or dislodgement which may result in loss of stimulation, intermittent stimulation, or pain at the Neurostimulator site.

After being implanted with the Neuspera SNM System, patients should refrain from manipulating the Neurostimulator. Pushing on or rubbing the Neurostimulator site may cause Neurostimulator damage, dislodgement, uncomfortable stimulation or pain at the Neurostimulator site.

3.4. Adverse Events

Below is a list of the potential adverse effects 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)
- 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
- Implant fracture/failure
- Implant migration
- 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, hemorrhage, and/or hematoma
- 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

4. SUMMARY OF CLINICAL EVALUATIONS

4.1. Introduction

Neuspera conducted a clinical study (IDE number G190064) to determine the safety and effectiveness of the Neuspera Sacral Neuromodulation (SNM) System for the treatment of urinary urge incontinence (UUI). The study design and data are summarized below.

4.2. Study Design

The SANS-UUI pivotal study (“Neuspera pivotal study”) was a prospective, multi-center, single-arm study to evaluate the safety and effectiveness of the Neuspera SNM System in the treatment of UUI. The study included patients with UUI who failed, could not tolerate, or were not a candidate for more conservative treatments, and 128 patients were implanted with the Neuspera SNM System. The SANS-UUI pivotal study was conducted in 29 clinical sites in the U.S. and 2 sites in Europe. The study evaluates the safety and effectiveness of the Neuspera SNM System after all subjects reached their 6-month visit. Additional data was collected beyond 6 months, including secondary endpoints at 12 months; see Figures 1 and 2 for the patient follow-up timepoints. The primary effectiveness endpoint is defined as the percentage of all patients with an attempted implant who experience an improvement in their UUI symptoms of at least 50% or more (“therapy responders”). A therapy responder is defined as experiencing $\geq 50\%$ reduction in the number of UUI episodes at 6 months after implant, compared to number of UUI episodes at baseline. The primary safety endpoint is defined as the number of device-related SAEs through the 6-month post-implant visit.

Table 5 shows the inclusion and exclusion criteria for the study.

Table 5: Inclusion and Exclusion Criteria

General inclusion criteria:	
1.	Is willing and able to understand and has voluntarily signed and dated the current approved informed consent.
2.	Is male or female 22 years of age or older.
3.	Has a Body Mass Index (BMI) greater than or equal to 18 and less than or equal to 40 kg/m ² .
4.	Is a good surgical candidate and is capable of participating in all testing and follow-up clinic visits associated with this clinical study and is capable of independently using the system components as described in the Patient Manual.
5.	Is ambulatory and able to use toilet without assistance.
6.	Has a diagnosis of UUI for greater than or equal to 6 months prior to the screening baseline visit date.
7.	Has typical residual bladder volume <150 cc tested within 6 months prior to the screening baseline visit date or is willing to have a test at screening baseline visit.
8.	Has urodynamic testing (uroflowmetry, cystometry, and pressure flow) completed within 6 months prior to the screening baseline visit date or is willing to have testing at the screening baseline visit.
9.	Has cystoscopy testing completed within 6 months prior to the screening baseline visit date or is willing to have a test at the screening baseline visit.

10. Has failed or was not a candidate for more conservative treatment (e.g., pelvic floor exercise, biofeedback, behavioral modification) 11. Has failed, could not tolerate (stopped taking medication due to lack of efficacy or intolerable side effects), or not a good candidate for (as determined by treating physician) at least one (1) antimuscarinic or β_3 adrenoceptor agonist medication. 12. Is willing and able to washout (at least five half-lives) from OAB medications for a period determined appropriate based on type of OAB medication prior to the baseline bladder diary and remain off OAB medications through the 12-month follow-up visit. 13. Has appropriate sacral anatomy as determined by sponsor's and investigator's analysis of radiographic imaging. (The distance from the surface of the skin in the prone and seated position to the bone edge of the S3 foramen must be within the capabilities of the system).
Baseline Bladder Diary Inclusion Criteria:
14. Has a diagnosis of UUI with at least 4 UUI episodes on a 72-hour diary, and minimum of one (1) UUI episode per 24-hour period.
General exclusion criteria:
1. Has a hemoglobin A1c of >8%, or has diabetes mellitus with glucosuria. 2. Has diabetic neuropathy. 3. Has interstitial cystitis or bladder pain syndrome as defined by either American Urological Association (AUA) or European Association of Urology (EAU) guidelines, chronic pelvic pain, or recurrent symptomatic urinary tract infections. 4. Has skin, orthopedic, neurological, or hematological (bleeding disorder) or anatomical limitations that could prevent successful placement of the neurostimulator. 5. Has broken, blistered skin or compromised circulation in the area of the neurostimulator implant. 6. Has neurogenic bladder dysfunction such as traumatic or atraumatic myelopathy, multiple sclerosis, Parkinsonism, or history of cerebrovascular accident. 7. Has documented urinary retention within 6 months prior to the screening baseline visit date. 8. Has clinically significant bladder outlet obstruction. 9. Is currently undergoing or has previously undergone pelvic irradiation. 10. Is a subject with a mechanical obstruction such as benign prostatic hypertrophy, urethral stricture, or cancer. 11. Has current grade 3 or 4 pelvic organ prolapse including cystocele, rectocele, enterocele, procidentia, or vaginal vault prolapse. 12. Has symptomatic urinary tract infection (UTI); the subject may be considered for study enrollment if the subject is symptom-free after a full course of treatment prior to beginning the baseline bladder diary. If an asymptomatic bacteriuria is detected during the urinalysis performed at screening, a subject may be enrolled without a waiting period relative to UTI treatment. 13. Has primary stress incontinence or mixed incontinence where the stress component predominates or has been treated surgically for stress urinary incontinence within 6 months prior to the screening baseline visit date.

14. Has received tibial nerve stimulation (TNS) in the past 3 months for the treatment of overactive bladder or unwilling to stay off TNS therapy for 12-month period following implant.
15. Has received treatment of urinary symptoms with any botulinum neurotoxin type-A (BoNT-A) agent in the past 12 months; (e.g. onabotulinumtoxinA, Botox®, abobotulinumtoxinA, Dysport®, IncobotulinumtoxinA, Xeomin®).
16. Is a woman who is pregnant or planning to become pregnant during this clinical study or is a woman of child-bearing potential who is not using a medically acceptable method of birth control. Women of child-bearing potential must undergo a pregnancy test, with clear negative result.
17. Has active substance abuse, including alcohol.
18. Has a known hypersensitivity or contraindication to procedural or post-procedural medications which cannot be adequately managed medically.
19. Has a known hypersensitivity to Neuspera's SNS System device components.
20. Has previously failed SNS therapy.
21. Has active implantable medical devices such as neurostimulators, drug pumps, pacemakers, or internal defibrillators since compatibility has not been assessed.
22. Has known needs for diathermy (shortwave, microwave, or therapeutic ultrasound), and radiofrequency ablation in the vicinity of the neurostimulator since these procedures have not been evaluated.
23. Has a known need for therapeutic ultrasound in the area of the sacral nerve neurostimulator as the device can inadvertently concentrate the ultrasound field and cause harm.
24. Has a known need for therapeutic ionizing radiation as can damage the electrical components of the sacral nerve stimulator and any damage may not be immediately detectable.
25. Has plans to enroll or is currently enrolled in another investigational device or drug trial during his/her participation in this study.
26. The investigator is unable to elicit an appropriate motor response in the subject during the intra-operative testing of the implant procedure.

4.2.1. Patient Disposition

34 sites were activated, and 31 sites enrolled 242 patients. At 25 sites, 130 patients had implants attempted, and 128 patients were successfully implanted. See **Figure 4** for the patient disposition at the time of database lock for the 12-month analysis. At the time of the 12-month database lock, the reasons for withdrawal of enrolled subjects are summarized as follows: patients who did not meet eligibility criteria, 33.1% (80/242); withdrew consent, 10.3% (25/242); patients not satisfied with therapy, 3.7% (9/242); patients lost to follow-up, 2.5% (6/242); patients withdrawn by investigator, 1.7% (4/242); patients withdrawn as the sites were terminated by the sponsor, 1.7% (5/242); patients withdrawn due to adverse event, 1.2% (3/242); implant attempted but not completed, 0.8% (2/242); patient deceased, 0.4% (1/242); and were withdrawn for other reasons, 2.9% (7/242).

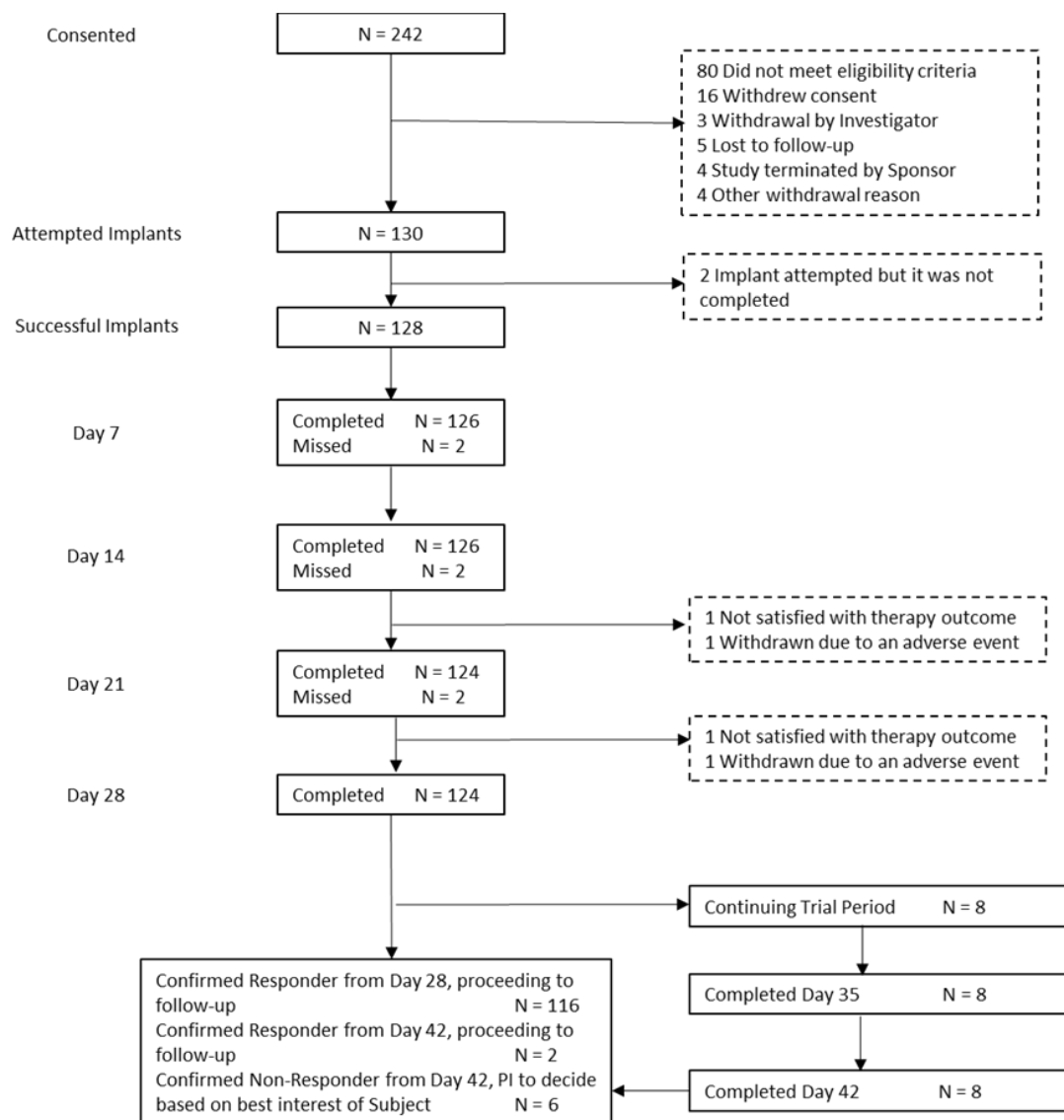


Figure 4: Patient Disposition – Post Implant Period

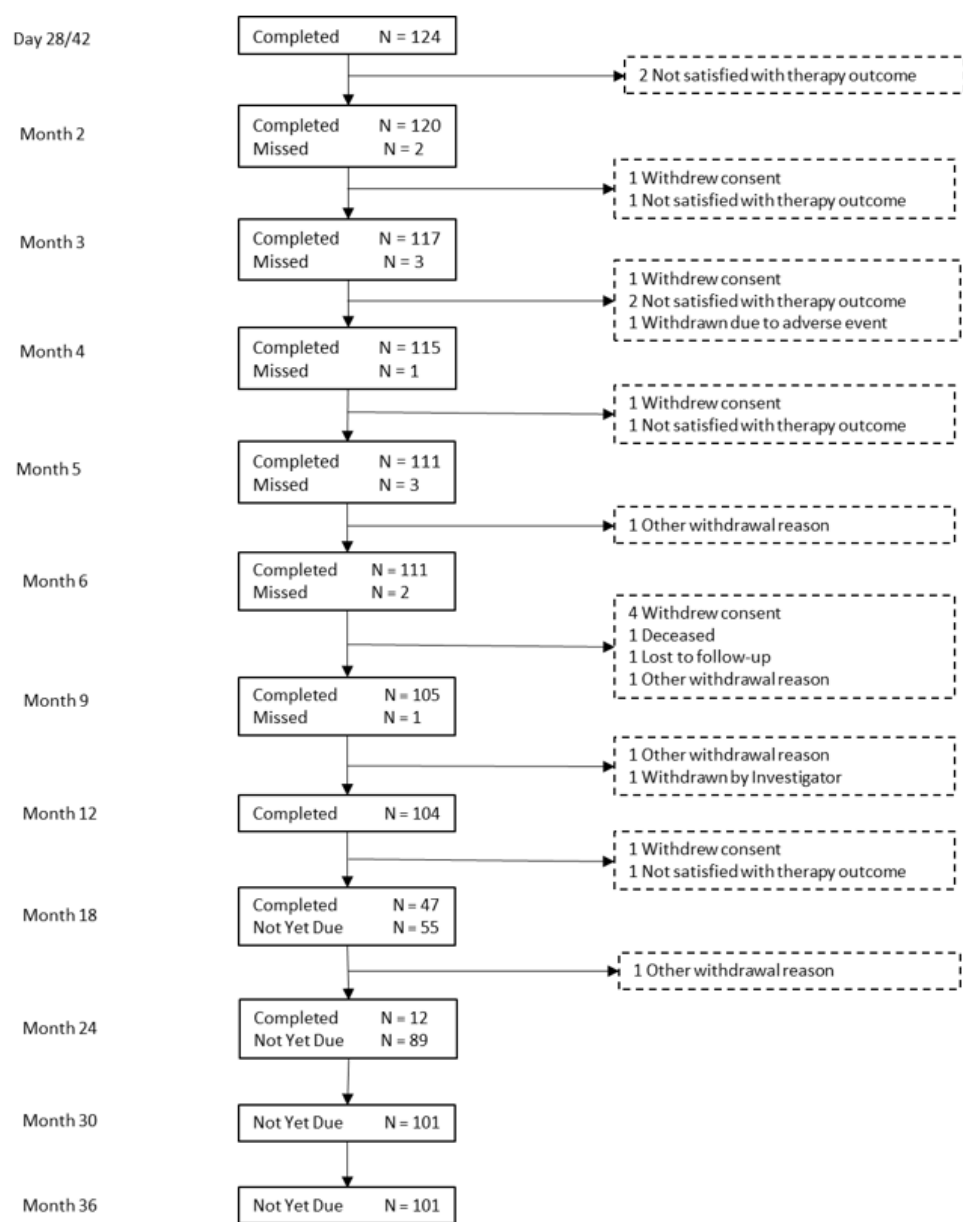


Figure 4: Patient Disposition – Post Implant Period (continued)

4.2.2. Analysis Sets

The analysis sets were pre-specified in the protocol as follows:

- **Intent-to-Treat (ITT) Analysis Set:** The ITT analysis set is defined as all patients who have signed informed consent.
- **Modified Intent-to-Treat (mITT) Analysis Set:** The modified Intent-to-Treat (mITT) Analysis Set is defined as all patients for whom an initial implant is attempted.

- **Implanted Analysis Set:** The Implanted analysis set is defined as all patients who are implanted with the Neuspera SNS system.
- **Responder Analysis Set:** The Responder analysis set is defined as patients who are implanted with the system and are defined as responders at the Day 28 or Day 42 clinic visit post-implant.
- **Per Protocol (PP) Analysis Set:** The Per Protocol analysis set is defined as implanted patients who have no protocol deviations that may significantly affect the primary endpoints. The determination of patients excluded from the Per Protocol analysis set was made prior to analysis.
- **Worst Case Analysis Set:** The Worst Case analysis set assumes that all patients with missing data were failures.

4.2.3. Patient Demographics and Baseline Characteristics

Demographics

Table 6 shows the baseline demographics of the mITT patients.

Table 6: Baseline Demographics

Baseline Characteristics	mITT (n = 130)
Age (years)	
N	130
Mean $\pm$ SD	60.4 $\pm$ 10.2
Median	61.0
Min, Max	21.0, 83.0
BMI	
N	130
Mean $\pm$ SD	29.5 $\pm$ 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)
Not Hispanic or Latino	120/130 (92.3)

Incontinence History

Table 7 presents the patients' incontinence history as reported at the baseline visit.

Table 7: 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	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

Patients in the mITT analysis set had a baseline of 4.5 ($\pm$ 2.5 SD) UUI episodes per day. See **Table 8** for the mITT patients categorized by severity of their UUI symptoms at baseline.

Table 8: 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 9 presents the patients' UUI treatment history as reported at baseline.

Table 9: 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 β 3 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)

4.2.4. Safety Results

Safety was demonstrated by a review of all Adverse Events (AEs). There were no device-related severe adverse events (SAEs) through the 12-month post-implant visit. There were a total of 338 adverse events in 108/130 (83.1%) patients, and 27 severe adverse events in 21/130 (16.2%) of patients in patients who had an attempted implant. One SAE was determined possibly related to the implant procedure. There were a total of 27 device-related events in 21 of 130 (16.2%) patients, and 21 procedure-related events in 19 of 130 patients (14.6%). Thirteen (13) events were definitely related to the device and one event definitely related to implant procedure.

There were 2 device fractures, 5 device migrations in 4 patients, 4 revisions, and 15 device explants at 6-months. At 12-months, there were a total of 5 device revisions and 21 explants. At 12 months, the number of device fractures and migrations did not change from 6 months. The majority of the migrations occurred within the first month of implant, and the fractures occurred on Day 26 and Day 63. However, one additional device fracture was seen after the 12-month data lock and was attributed to chiropractic manipulation. **Table 10** shows the fractures, migrations, and revisions that occurred through the 12-month datalock.

Table 10: Fractures, Migrations, Revisions, and Explants through 12 months post-implant

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

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

Table 11 shows the device-related adverse events, and **Table 12** shows the procedure-related adverse events through the 12-month post-implant visit.

Table 11. Device-Related Adverse Events through 12-months post-implant – mITT Analysis Set (N = 130)

	Events n	Patients n/N (%) ²
Total Device-Related Adverse Events¹	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 12: Procedure-Related Adverse Events through 12 months post-implant – mITT Analysis Set (N = 130)

	Events n	Patients n/N (%)²
Total Procedure-Related Adverse Events¹	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%)

¹As coded by the Clinical Events Committee chairperson.

² Exact 95% confidence Interval.

Table 13 shows device- related AEs as a function of time after implant through the 12-month visit database lock.

Table 13: Device-Related AEs Over Time (from Implant Date) – mITT Analysis Set (N = 130)

Device-Related AEs	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
Radicular pain			1				1
Urinary tract infection						1	1
Vulvovaginal pain		1					1

Table 14 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 14: 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
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

4.2.5. Effectiveness Result

Six-Months Results (Primary Endpoint)

For patients with an attempted implant (N=130), 82.9% of patients at Month 6 were responders ($\geq 50\%$ reduction from baseline in UIIs per day). The study met the 50% performance goal at 6 months, as summarized in **Table 15** below.

Table 15. Responder Rate in UII Summary at Month 6 – mITT Analysis Set (n=130) - Imputed

	Estimate (%)	Lower 95% CI	Upper 95% CI	P-value (2-sided)
Patients with $\geq 50\%$ reduction from baseline in UIIs per day	82.9%	76.4%	89.4%	<0.0001

Note: The imputation model includes baseline age, investigational site, baseline UII episodes, and all available follow-up visit UII episodes through 6 months. It uses full conditional specification and 100 imputed data sets.

The primary endpoint was also analyzed for additional study groups at 6 months, as summarized in **Table 16** below.

Table 16. Primary Endpoint for Various Analysis Sets at Month 6 - Imputed

Patients with $\geq 50\%$ reduction from baseline in UIIs 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. The estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

Note: The imputation model includes baseline age, investigational site, baseline UII/ episodes, and all available follow-up visit UII episodes through 6 months. It uses full conditional specification and 100 imputed data sets.

Table 17 presents data imputed for primary endpoint sub-group analysis at 6 months, based on the responder rate for UII episodes, for sex, age, race, baseline UII episodes and geographic region.

Table 17: Primary Endpoint Subgroup Analysis at Month 6 – mITT Analysis Set (N = 130) - Imputed

Patients with $\geq 50\%$ reduction from baseline in UIIs per day	Estimate (%)	Lower 95% CI	Upper 95% CI³
Female (N=128)	82.6%	76.0%	89.2%
Male ¹ (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 UIIs <8 (N=117)	84.4%	77.8%	91.0%
Baseline UIIs ≥ 8 ² (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%

¹ The subgroup does not contain any missing response values following the imputation of failures. Therefore, the estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

² The subgroup contains a single missing response value. The imputation model results in zero between-imputation variance. Therefore, the single missing value is imputed with the result of the multiple imputation value for that patient, and estimate is based on the data summary without multiple imputation modelling. Z-test statistic is displayed instead of t.

³ If the imputation results in an upper 95% CI >100%, the value will be forced at 100%.

Note: The imputation model includes baseline age, investigational site, baseline UII episodes, and all available follow-up visit UII episodes through 6 months. It uses full conditional specification and 100 imputed data sets.

Table 18 shows the secondary effectiveness endpoints related to urinary symptoms at 6 months.

Table 18. Secondary Effectiveness Results at Month 6 – mITT Analysis Set (N=130) - Imputed

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

The imputation model includes baseline age, investigational site, baseline data, and all available follow-up measures through 6 months. It uses full conditional specification and 100 imputed data sets.

For the secondary effectiveness endpoints in **Table 18**, the first three endpoints (i.e., reduction from baseline in the mean number of UUI episodes per day, improvement from baseline in ICIQ-OABqol score, and the percentage of patients who experienced an improvement in ICIQ-OABqol of at least 10 points) supported the findings from the primary endpoint in improvement in 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 patients with an attempted implant (N=130), 77.7% of patients at Month 12 were responders (≥ 50% reduction from baseline in UUIs per day), as summarized in **Table 19** below.

Table 19. Responder Rate in UUI Summary at Month 12 – mITT Analysis Set (n=130) - Imputed

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

Note: The imputation model includes baseline age, investigational site, baseline UUI episodes, and all available follow-up visit UUI episodes through 12 months. It uses full conditional specification and 100 imputed data sets.

This endpoint was also analyzed for additional study groups, as summarized in **Table 20** below.

Table 20. Responder Rate for Various Analysis Sets at Month 12 - Imputed

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. The estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

Note: The imputation model includes baseline age, investigational site, baseline UUI episodes, and all available follow-up visit UUI episodes through 12 months. It uses full conditional specification and 100 imputed data sets.

Table 21 presents data imputed for primary endpoint sub-group analysis at 12 months, based on the responder rate for UUI episodes, for sex, age, race, baseline UUI episodes and geographic region.

Table 21: Responder Rate Endpoint Subgroup Analysis at Month 12 – mITT Analysis Set (N = 130) - Imputed

Patients with ≥ 50% reduction from baseline in UUIs per day	Estimate (%)	Lower 95% CI	Upper 95% CI ³
Female (N=128)	77.4%	70.0%	84.8%
Male ¹ (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 ¹ (N=7)	57.1%	20.5%	93.8%
Baseline UUIs <8 (N=117)	79.5%	72.0%	87.0%
Baseline UUIs ≥8 ² (N=13)	61.5%	35.1%	88.0%
US (N=124)	77.5%	70.0%	85.0%
EU ¹ (N=6)	83.3%	53.5%	100.0%

¹ The subgroup does not contain any missing response values following the imputation of failures. Therefore, the estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

² The subgroup contains a single missing response value. The imputation model results in zero between-imputation variance. Therefore, the single missing value is imputed with the result of the multiple imputation value for that subject, and estimate is based on the data summary without multiple imputation modelling. Z-test statistic is displayed instead of t.

³ If the imputation results in an upper 95% CI >100%, the value will be forced at 100%.

Note: The imputation model includes baseline age, investigational site, baseline UUI episodes, and all available follow-up visit UUI episodes through 12 months. It uses full conditional specification and 100 imputed data sets.

Table 22 shows the secondary effectiveness endpoints related to urinary symptoms at 12 months post-implant.

Table 22. Secondary Effectiveness Results at Month 12 – mITT Analysis Set (N=130) - Imputed

Effectiveness Measure (n=130)	Month 12
Reduction from baseline in the mean number of UUI episodes per day ¹	2.96 ± 2.57
Improvement from baseline in ICIQ-OABqol score ²	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) ³	84.4%
Reduction from baseline in Urgent Episodes ⁴	1.14 ± 2.70
Reduction in average number of daily voids in patients with at least 8 voids at baseline ⁵	1.67 ± 5.17

The imputation model includes baseline age, investigational site, baseline data, and all available follow-up measures through 12 months. It uses full conditional specification and 100 imputed data sets.

4.3. Conclusions

4.3.1. Effectiveness Conclusions

The results from the SANS-UUI study show that SNM therapy provides a clinically meaningful improvement in symptoms of urge urinary incontinence in patients who have failed, could not tolerate, or were not a candidate for more conservative treatments. For the mITT analysis set, 82.9% and 77.7% of patients had a $\geq 50\%$ reduction from baseline in UUIs per day at 6 months and 12 months post-implant, respectively.

The secondary effectiveness endpoints in the clinical study as measured by improvements in urinary symptoms including reduction in UUI episodes and ICIQ-OABqol scores also supported improvement in symptoms of UUI by the Neuspera SNM System.

4.3.2. Safety Conclusions

In the SANS-UUI study of the Neuspera SNM System, there were no serious device-related AEs and one serious procedure-related AE reported. At the twelve-month endpoint, there were a total of 27 device-related events in 21 of 130 (16.2%) patients and 21 procedure-related events in 19 of 130 patients (14.6%).

At the twelve-month endpoint, the most common device-related AEs in the SANS-UUI study were implant migrations (3.1% of patients), device stimulation issue (2.3%), implant fractures (1.5%), implant site pain (1.5%), medical device pain (painful stimulation due to high amplitude stimulation or after a fall) (1.5%), and medical device site burn (WT placed directly on skin) (1.5%). No other device-related AE occurred more than once ($<0.8\%$ of patients). There were no infections at the site of the implant.

At 12 months, there were 2 device fractures, 5 device migrations in 4 patients, 5 revisions, and 21 device explants. The majority of the migrations occurred within the first month of implant, and the fractures occurred on Day 26 and Day 63. However, one additional device fracture was seen after the 12-month data lock and was attributed to chiropractic manipulation.

5. USE ENVIRONMENTS

Neuspera procedures will occur in hospitals, surgery centers, and clinics.

6. CLINICIAN INSTRUCTIONS FOR USE

Do not detach or disassemble devices, or use accessories not described in this manual. The system may not function according to specification under these conditions.

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

6.1. Patient Selection

Patients should be appropriate candidates for therapy evaluation and for potential surgical implant of an SNM system. Patients are contraindicated for therapy evaluation if their sacral depth measured from skin to the S3 foramen is greater than 10 cm as confirmed by imaging and they are unable to properly operate the Trial System.

The Trial System is intended to be used continuously during the stimulation trial. If the patient experiences a 50% reduction in urinary urge incontinence symptoms after the trial stimulation, they may proceed to receive a permanent system.

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

The safety and effectiveness of using the Neuspera System have not been established in the following:

- Patients with BMI > 40,
- Pregnant women,
- Pediatric patients,
- Bilateral stimulation with the permanent Neuspera SNM System (bilateral stimulation may be used with Trial System),
- Patients with neurologic cause of OAB such as multiple sclerosis, diabetes, or Parkinson's disease.

6.2. Neurostimulation Trial

The Neuspera SNM Trial System is used for a test period to evaluate if a patients should be treated with the Neuspera Permanent SNM System. Trial stimulation should not exceed 7 days. Patients should experience a 50% reduction in urinary urge incontinence symptoms prior to proceeding to a permanent implant.

6.3. Neurostimulator Implantation

Refer to the Neuspera Sacral Nerve Stimulator Implant Kit Instructions for Use for details of the Neurostimulator implantation procedure.

IMPORTANT:

- Ensure that x-ray imaging according to the Neuspera Radiographic Imaging Guidance is conducted and that sacral depth assessment is conducted and approved by Neuspera prior to the implantation procedure.
 - **NOTE:** If the sacral depth is too great, the Neuspera SNM System should not be used as the implant may not be able to be powered and may require an explant. For these patients, a different SNM device should be selected.
- A Neuspera Field Clinical Engineer (FCE) is required to be present at each implantation procedure. Please contact your local sales representative or call (888) 846-8332 or email Physicianhelp@neuspera.com to ensure an FCE will be present at the procedure.

6.4. Intraoperative Neurostimulator Functionality Check

After the Neurostimulator has been implanted, the functionality of the Neurostimulator should be checked with the patient's Wireless Transmitter prior to sending the patient to post-operative recovery.

1. Assign at least 1 Wireless Transmitter to the patient's Neurostimulator (see "Setting up a Patient Profile," and "Wireless Transmitter Management" sections).
2. Adjust therapy parameters on the Clinician Programmer as needed (see "Therapy Configuration" section).
3. Using a sterile technique, use a sterile sleeve around the Wireless Transmitter.
4. Carefully place the Wireless Transmitter over the Neurostimulator site.
5. When stimulation is desired, enable therapy via the App on the Clinician Programmer.

Note: You can stop stimulation on the App by tapping the Power "switch" to move it to the off position or removing the Wireless Transmitter from the Neurostimulator site.

6. When the Wireless Transmitter is powering the implanted Neurostimulator, document all physiological responses to the stimulation in the patient record including:
 - Bellows
 - Flexion of the great toe or other toes
 - If the patient is under conscious or local sedation, ask the patient for a sensory response confirmation
7. If no physiological response is seen:
 - Increase the stimulation amplitude through the Clinician Programmer and/or
 - Slowly move the Wireless Transmitter around the implantation site (translate relocate and/or rotate)
8. Repeat steps 2-7, as necessary, to check the functionality of all electrodes.

6.5. Post-Operative Patient Training and Follow-up Instructions

After the patient has recovered from the procedure, the stimulation therapies programmed to the Wireless Transmitter (see “Setting up a Patient Profile” and “Wireless Transmitter Management” sections of this manual) should be checked to ensure that the stimulation amplitude is high enough for the patient to feel, but low enough to be comfortable. Be sure to check all programs. Ask the patient to describe the sensations (location and intensity) that they feel at different stimulation amplitudes and with the different pre-set programs. Daily therapy with the WT can begin after the patient has been programmed, usually the day after the implantation procedure.

6.5.1. Patient Training

1. Ensure the patient is provided with the following items:

- Wireless Transmitter
- Patient Controller and accessory cables
- Neuspera Undergarments in the proper size (multiple pairs)
- Charging Pad and accessory cables
- Magnet
- Patient ID card

Instruct the patient to contact the clinic to order replacement components or to dispose of system components, such as the Wireless Transmitter, Patient Controller, Magnet, or Charging Pad. For reprocessing, refer the patient to the Patient Manual sections on caring for the system, service life/ordering replacements, and safe disposal. See the section on Disposal Guidance.

2. Train the patient on how to insert and remove the Wireless Transmitter from the Undergarment pocket.
 - a. Instruct the patient that the Wireless Transmitter must only be worn in the Undergarment. This is important for patient safety and proper powering of the Neurostimulator.
 - b. Explain to the patient that it is normal for the Wireless Transmitter to get warm during therapy. If it becomes uncomfortably hot, they should turn it off or remove it. The Wireless Transmitter may interrupt therapy if an elevated temperature is detected. Programmed therapy will resume after the Wireless Transmitter temperature has sufficiently decreased.
3. Instruct the patient to always take a few moments at the beginning of every therapy session and periodically throughout the therapy session to ensure that they are feeling the sensations felt during the post-operative training session.
4. 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.
5. Have the patient walk around the room or up/down the hall while wearing the Wireless Transmitter to ensure that the Wireless Transmitter and Undergarment are comfortable, and that stimulation is still felt while moving around.
6. Have the patient move the Wireless Transmitter around and note when the stimulation is no longer felt. Instruct the patient to be sure to check that they can feel the stimulation at the beginning of each therapy session, or whenever the Undergarment is doffed or donned. Instruct

the patient to adjust the position of the Wireless Transmitter if stimulation is not felt. If proper positioning is difficult to achieve, have the patient try another Undergarment size.

7. Configure the Patient Controller for the patient (see “Patient Controller Connection” section below). Train the patient on how to use their Patient Controller App to adjust the stimulation amplitude and change stimulation programs (see the Neuspera Sacral Neuromodulation System Patient Manual).
8. If the patient is provided multiple Wireless Transmitters, instruct the patient to move all Wireless Transmitters other than the one they are wearing at least 3 meters (10 feet) from their Patient Controller. Instruct the patient on how to identify which Wireless Transmitter is connected to the Patient Controller App.
9. Instruct the patient that when the Wireless Transmitter needs to be reset, the patient will place the Wireless Transmitter correctly on the Charging Pad (dotted side face up). The label side of the magnet (bottom of magnet) is placed against the dotted side of the Wireless Transmitter for 5-10 seconds to perform the reset. The teardrop point of the magnet should be aligned with the teardrop point of the Wireless Transmitter (**Figure 5**). Ensure that the green light has stopped blinking when the magnet is placed on the Wireless Transmitter. After 5-10 seconds, remove magnet from the Wireless Transmitter. Do not leave magnet on Wireless Transmitter while it is charging.

The patient will confirm the reset was successful by observing the following:

1. Confirming the green light on the Wireless Transmitter is blinking.
2. Waiting 30 seconds and observing that the status light of the charging pad has initiated.

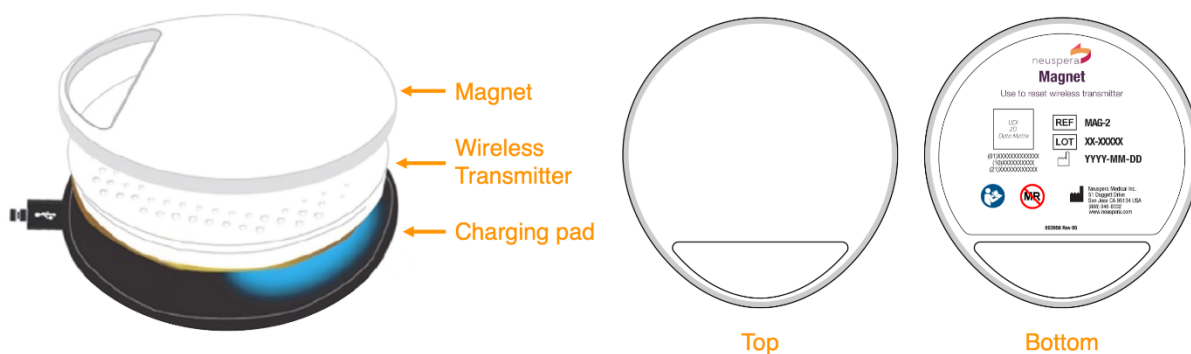


Figure 5: Resetting the Wireless Transmitter. Place the label side of the magnet (bottom of magnet) on the Wireless Transmitter for 5-10 seconds. The top of the magnet is visible during correct placement. Remove magnet after reset is completed. Do not leave magnet on Wireless Transmitter while it is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

10. Instruct the patient on proper bandage care during the first week following implantation of the Neurostimulator.
11. Remind the patient of the importance of adhering to the prescribed therapy to provide the best opportunity for symptom reduction.
12. Instruct the patients about electromagnetic interference (EMI). Most household appliances and equipment that are working properly and grounded properly will not interfere with the

Neuspera System. The following equipment is generally safe if patients follow these guidelines:

- Portable RF communications or wireless power transfer 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: Keep the Wireless Transmitter away from the burners while the burners 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

EMI from the following medical procedures is unlikely to affect the Neurostimulator. The Wireless Transmitter should be removed from the patient for all procedures:

- Computerized axial tomography (CT or CAT) scans.
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Diagnostic ultrasound

6.5.2. Patient Device Identification Card

A patient device identification card is included in the Neuspera Sacral Nerve Stimulator Implant Kit. Be sure to fill out the Neurostimulator model number (located on the Implant Kit label), serial number (located on the Implant Kit label and the proximal assembly of the neurostimulator), and implantation date, and provide it to the patient before discharge.

The figure displays two sides of a patient device identification card. The left side, titled "Implanted Neurostimulator", includes fields for patient name, address, city/state, telephone, model number, serial number, and implantation date. It also features the Neuspera logo and contact information. The right side, titled "patient has an implanted neurostimulator in case of emergency, contact:", includes fields for doctor's name and phone number. It also contains a warning about MRI safety and a reference to the MRI Safety Information section of the clinician manual.

Figure 6. Patient Device ID card

6.5.3. Patient Follow-up Instructions

Instruct the patient that they must bring all Wireless Transmitters, Charging Pad, Magnet and Patient Controller to all clinician physician visits to allow for adjustments to programming and to ensure the devices are functioning properly.

6.6. Clinician Programmer Overview

The Clinician Programmer enables management of the Wireless Transmitters associated with a patient's Neurostimulator, programming of a patient's stimulation therapy into their Wireless Transmitter, review of a patient's therapy statistics, and connection of a Patient Controller to a Wireless Transmitter.

There are four (4) primary views in the Clinician Programmer (**Figure 7**):

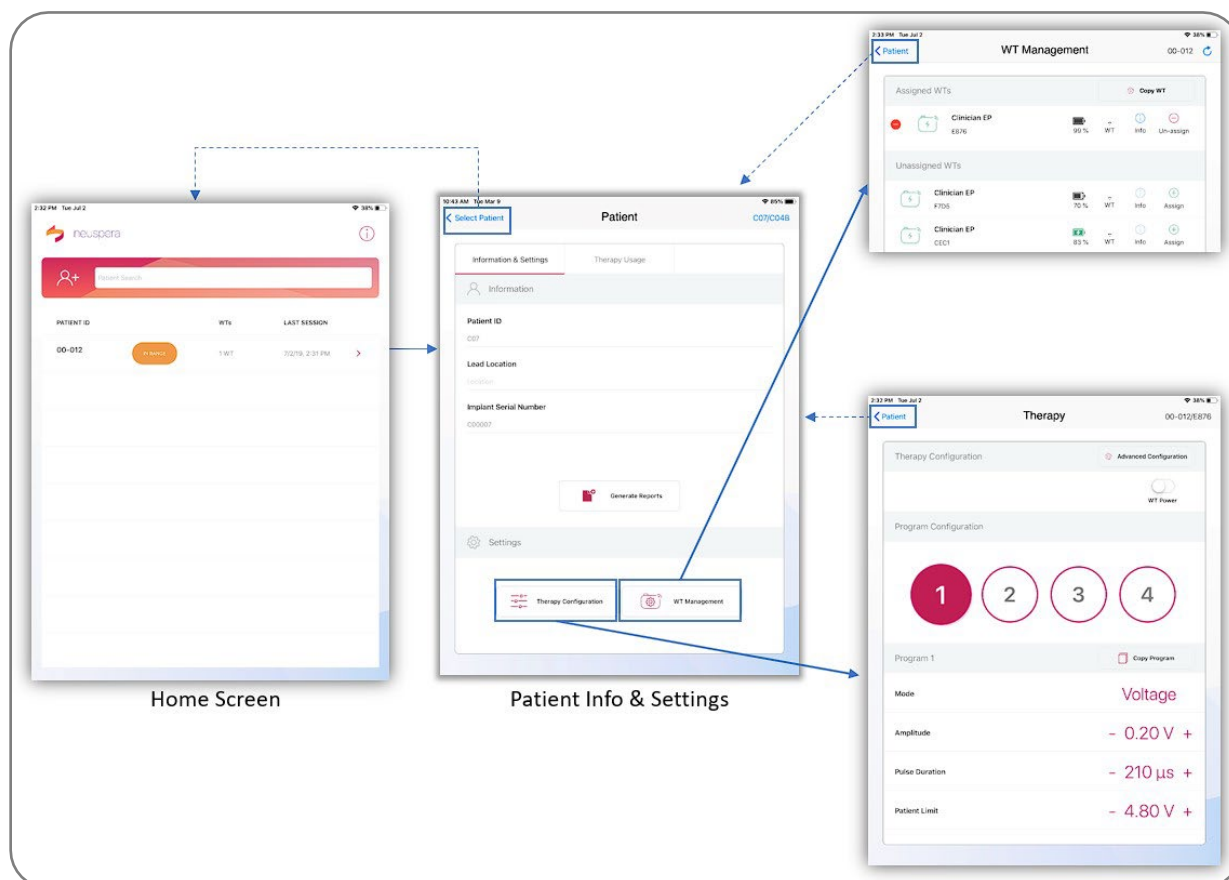


Figure 7. Navigating through the 4 most commonly used screens on the Clinician Programmer

6.7. Setting up a Patient Profile

To set up a new patient profile, tap the “add person” icon on the Home screen (**Figure 8**). This will open the patient profile page where you can enter the patient ID and Neurostimulator serial number (found on the Neurostimulator kit label).

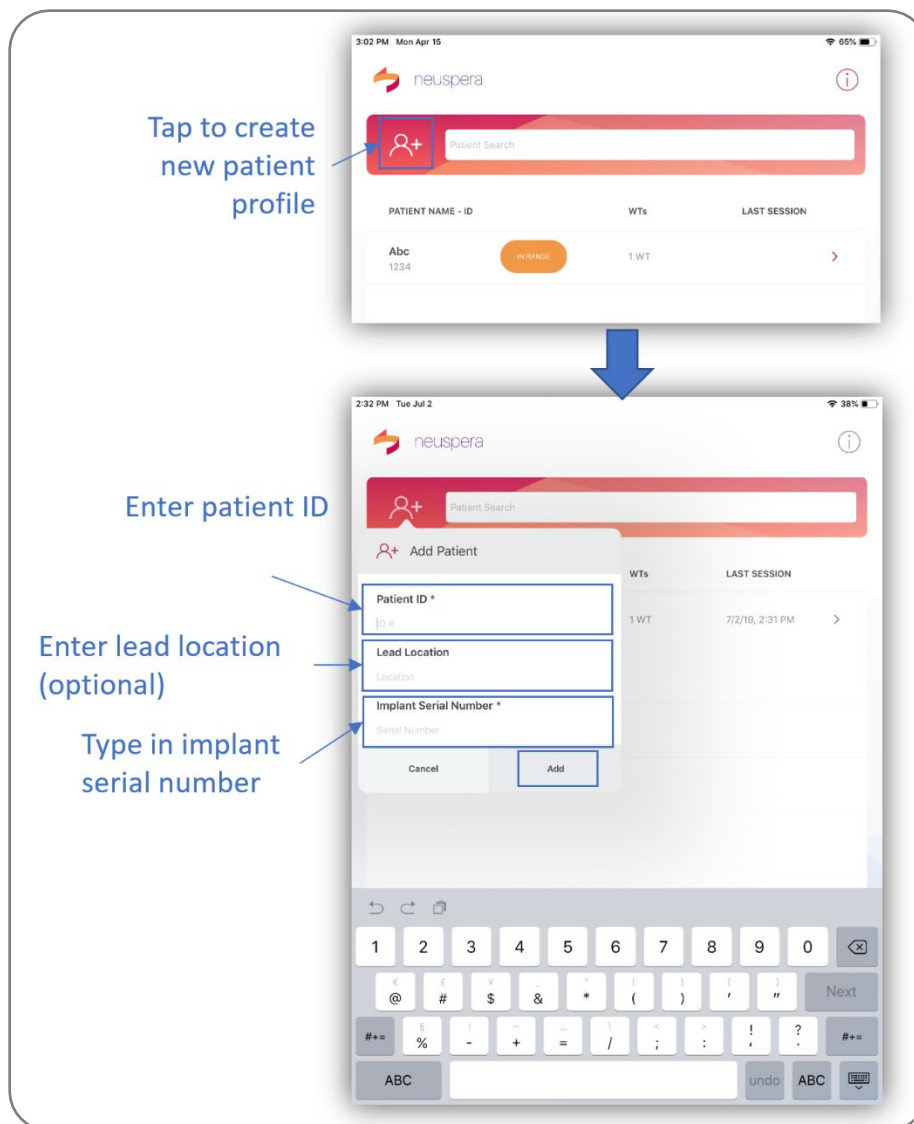


Figure 8. Setting up a new patient profile

Note: A Wireless Transmitter will not be able to link to the patient’s Neurostimulator unless the correct Neurostimulator serial number is entered.

6.8. Wireless Transmitter Management

To assign or unassign a Wireless Transmitter to a patient, tap on “WT Management” from the Patient Information & Settings screen (Figure 9).

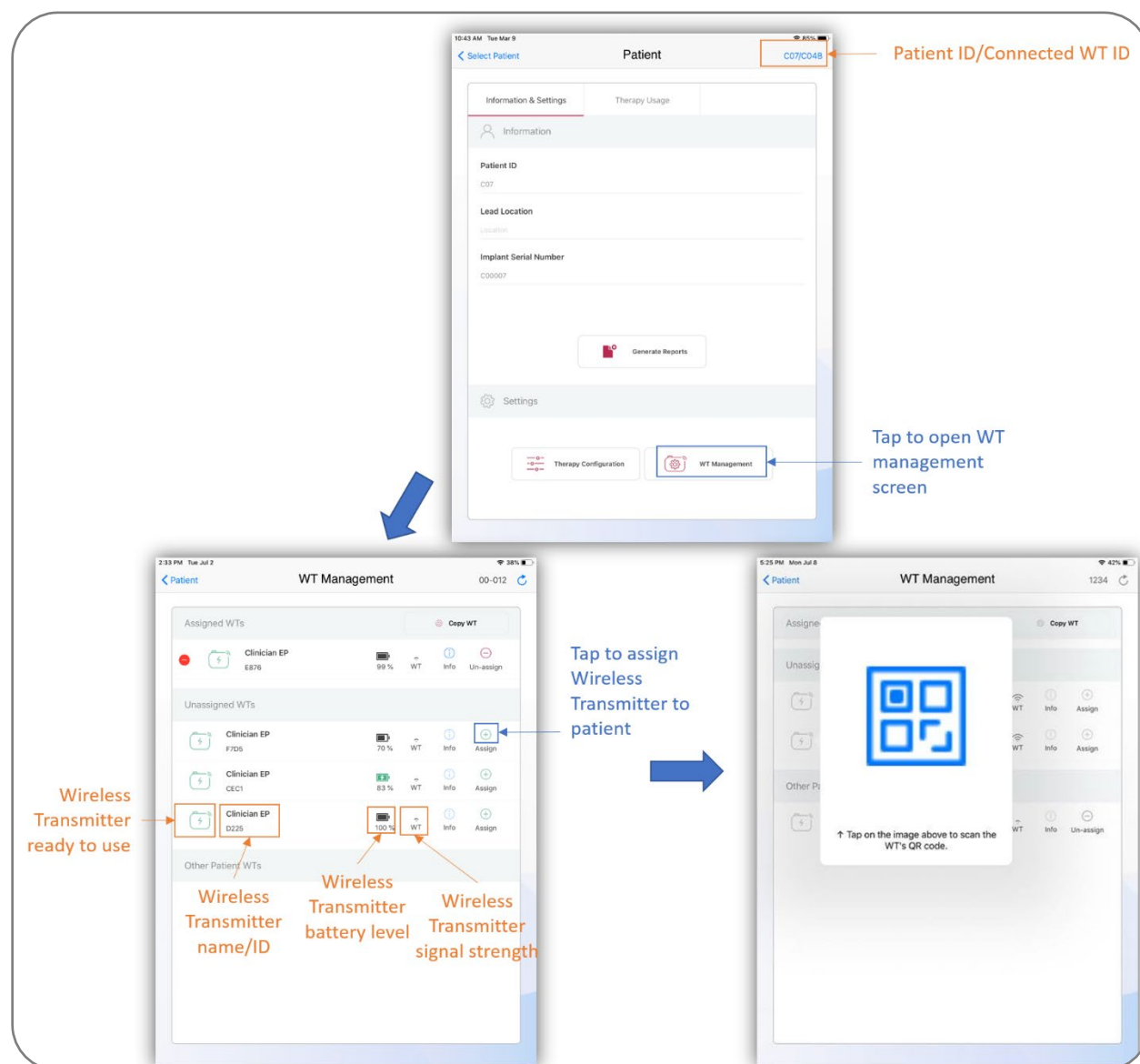


Figure 9. Assigning Wireless Transmitters to a patient's profile.

All Wireless Transmitters that are within range and transmitting a Bluetooth® signal will appear on the WT Management screen. Select an unassigned Wireless Transmitter and assign it to the patient by tapping the green “+” Assign icon.

After clicking “+”, the App must scan the QR code on the Wireless Transmitter to complete the authenticated assignment. Tap on the blue QR code icon to activate the device's camera and hold it over the QR code on the Wireless Transmitter (or Wireless Transmitter's box label) until the code is recognized (see **Figure 10** for locations of QR code on Wireless Transmitter and box label).

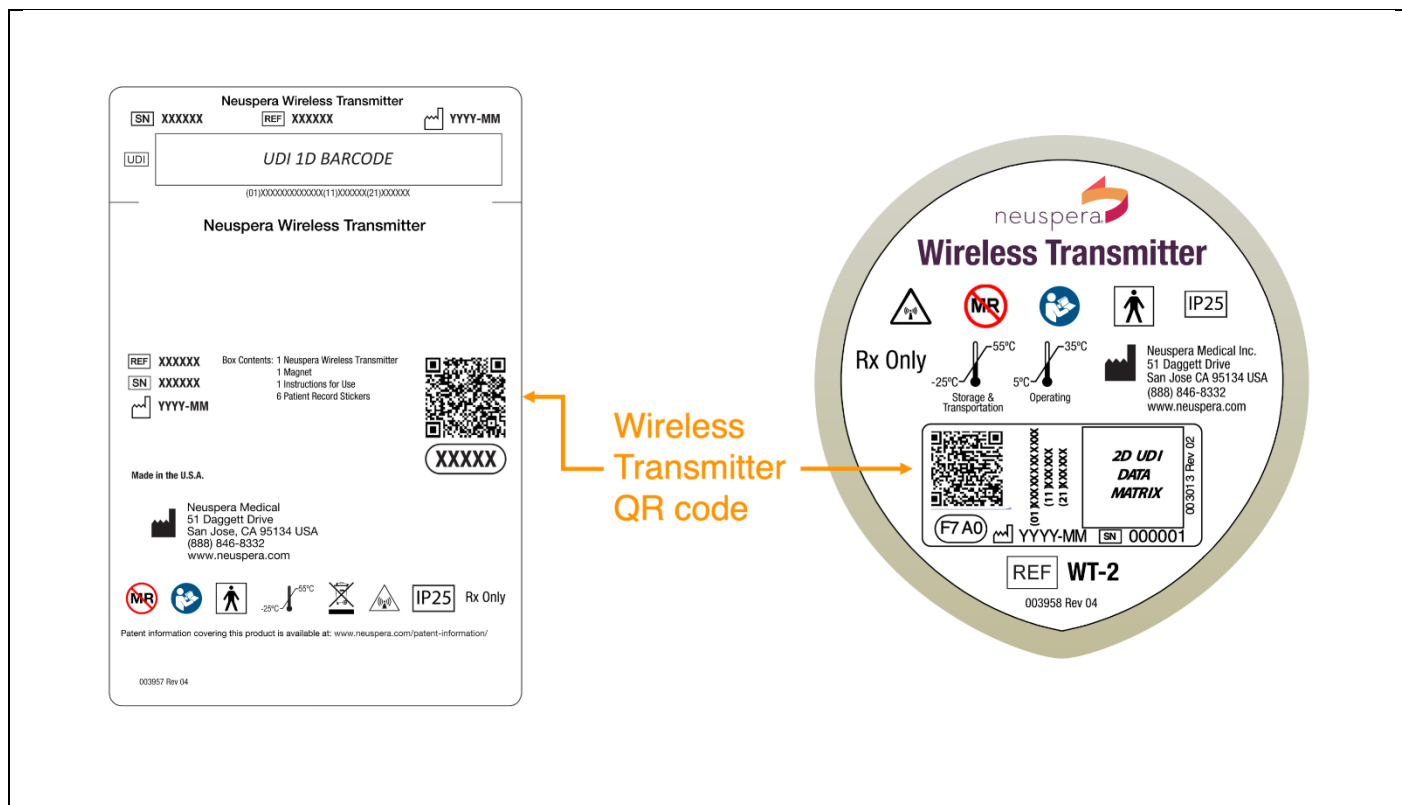


Figure 10. Location of Wireless Transmitter QR code on the Wireless Transmitter (left) and the Wireless Transmitter box label (right).

If an incorrect Wireless Transmitter is assigned to a patient, tap on the red “-” Unassign icon (**Figure 11**).

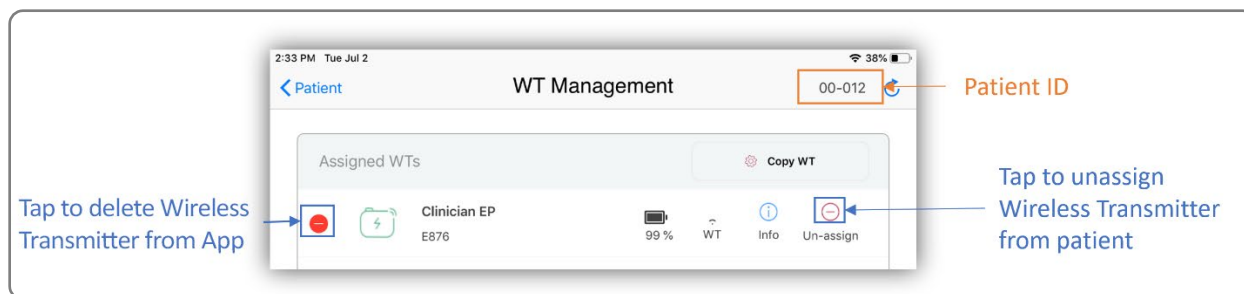


Figure 11. Unassigning a Wireless Transmitter from a patient's profile

Note: Do not use the Delete button to unassign a Wireless Transmitter from a patient. This will only delete the entry from this Clinician Programmer App view; it will not unassign the Wireless Transmitter from the patient, and the Wireless Transmitter will still appear on the Patient Controller.

6.9. Therapy Configuration

To set up or modify a patient's stimulation therapy, tap "Therapy Configuration" at the bottom of the Patient Information & Settings screen to open the Therapy screen (**Figure 12**).

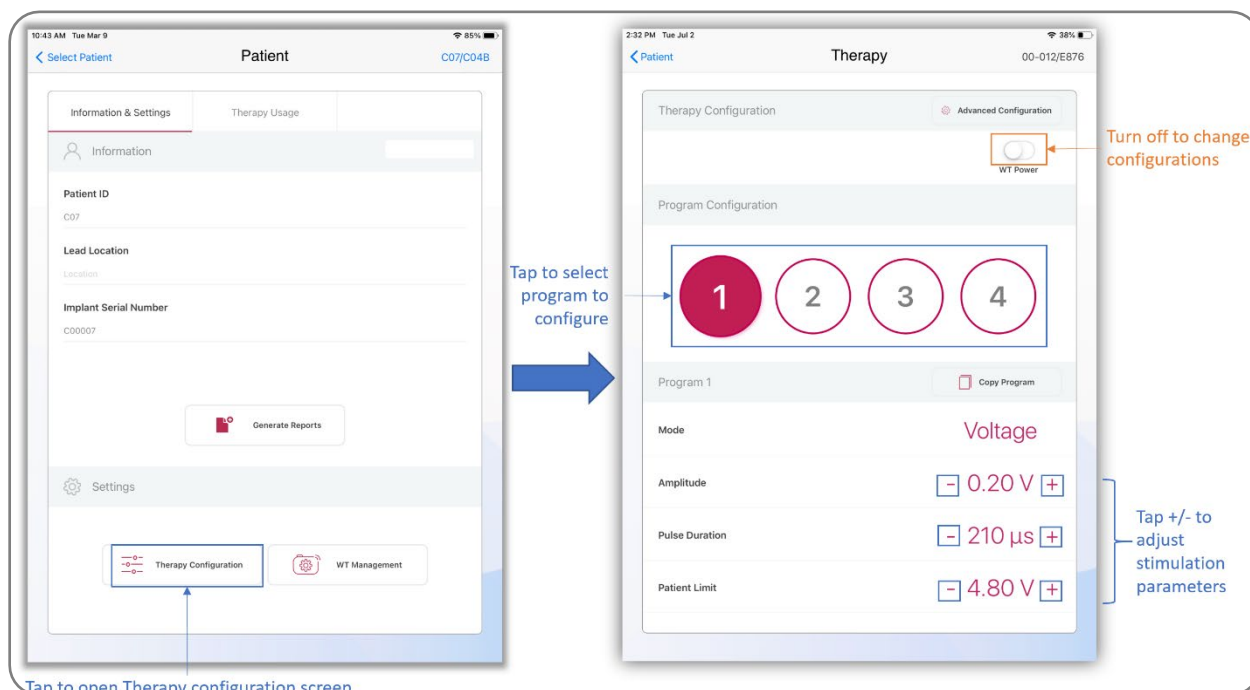


Figure 12. Therapy Configuration

6.9.1. Program Configuration

1. Tap on the circle "1" to start configuring program 1.
2. Tap on the Amplitude "-" to decrease or "+" to increase the stimulation amplitude (range 0.2-4.8 V in 0.1 V increments below 1.0 V and 0.2 V increments above 1.0 V).
3. Tap on the Pulse Duration "-" to decrease or "+" to increase the stimulation pulse duration (range 105-945 μ s in 15 μ s increments).
4. Tap on the Patient Limit "-" to decrease or "+" to increase the maximum stimulation amplitude to which the patient can increase stimulation.

Note: Amplitude is the only stimulation parameter the patient can change on their own for a given program.

5. Repeat the above steps for programs 2-4.

6.9.2. Advanced Configuration

To specify the electrode configuration, frequency (rate), and RF power level for each program, open the "Advanced Configuration" screen by tapping the button in the upper right corner of the Therapy screen (**Figure 13**).

Note: During initial intraoperative testing of the implanted Neurostimulator, the functionality of all electrodes should be tested by changing the electrode configuration (i.e. test electrodes 1 and 2 as cathode or anode in at least one configuration each).

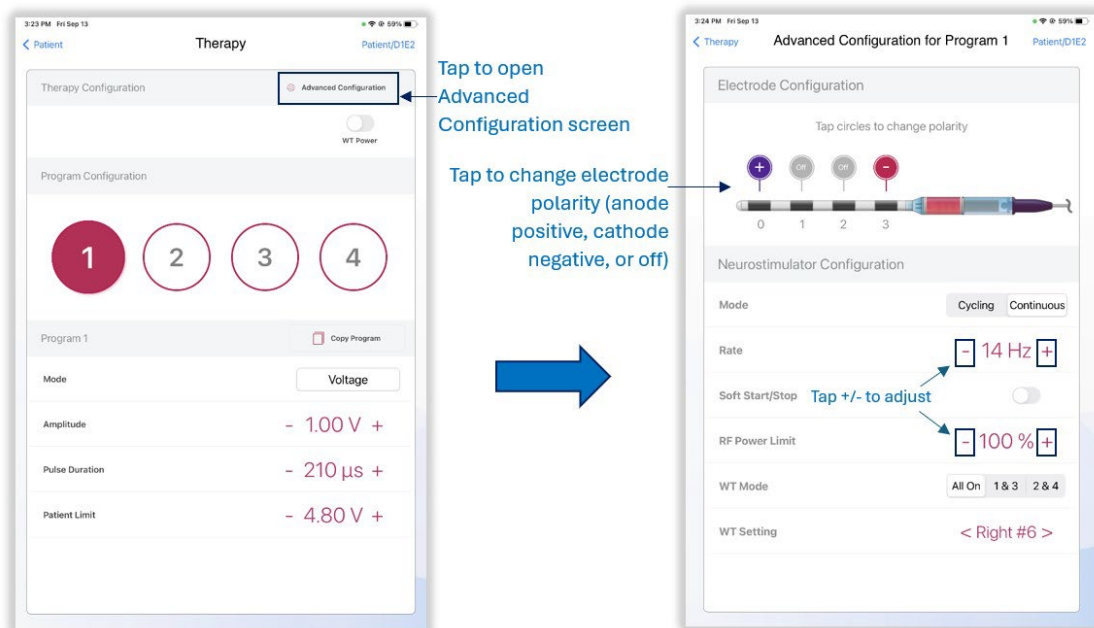


Figure 13. Advanced configuration screen to configure electrode settings

6.9.3. Patient Controller Connection

To allow a Patient Controller to view or adjust the therapy settings in the Wireless Transmitter, an authenticated link between the Patient Controller and the Wireless Transmitter must be established using the Clinician Programmer.

Click the “Info” icon on the WT Management screen to open a screen with a QR code unique to the patient’s Neurostimulator and assigned Wireless Transmitter (see **Figure 14**).

Note: The QR code generated by the Clinician App is NOT the same QR code that is on the Wireless Transmitter label.

See **Figure 11**, for how to prepare the Patient Controller for a new Wireless Transmitter connection.

- If the Patient Controller is not already connected to a Wireless Transmitter, the Patient Controller App will prompt to scan the QR code when the Patient Controller App is opened (**Figure 15**, left image).
- If additional Wireless Transmitters are being connected, tap on the prompt next to “Connect to a New WT” from the Patient Controller App Info screen (**Figure 15**, right image). This will open the QR prompt screen. Tap on the blue QR code icon to activate the camera on the Patient Controller and hold over the QR code displayed by the Clinician Programmer App.

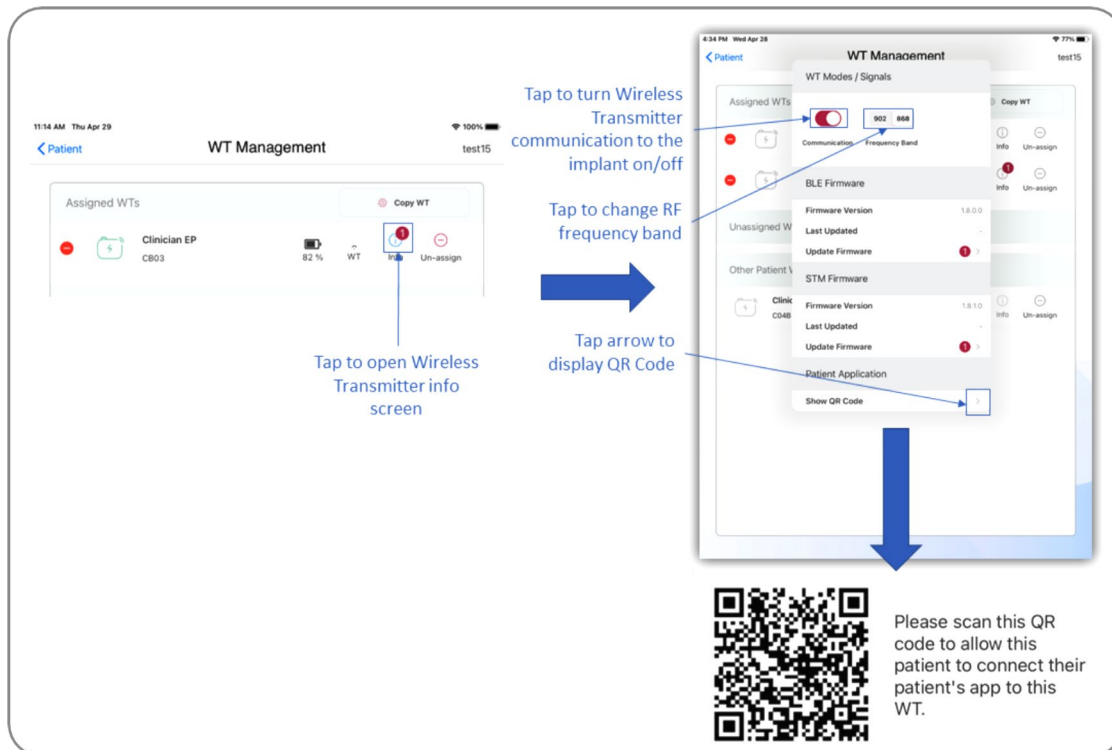


Figure 14. Wireless Transmitter info screen and QR code to connect a Wireless Transmitter to a Patient Controller.

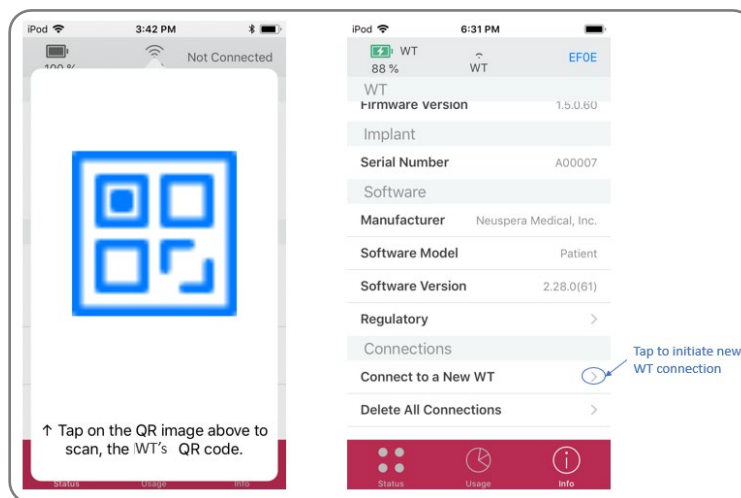


Figure 15. Patient Controller App screens for connecting to a Wireless Transmitter. Left image: QR code prompt to a New WT. Right image: App Info screen for a Patient Controller App already connected to at least one Wireless Transmitter.

Note: Only a single Patient Controller may be linked to a Wireless Transmitter. Connecting a second Patient Controller to a Wireless Transmitter will invalidate the authentication of the first Patient Controller.

6.9.4. Follow-up Visits

Instruct patients to always bring their Wireless Transmitter(s), Charging Pad(s), Magnet, Undergarments, and Patient Controller to all follow-up visits. The patient's Wireless Transmitter will need to be within range of the Clinician Programmer in order to view the usage history or adjust therapy programs. The Home screen of the Clinician Programmer App will list all the Wireless Transmitters that are associated with that specific Clinician Programmer. If necessary, enter the patient's ID using the search box at the top (Figure 16).

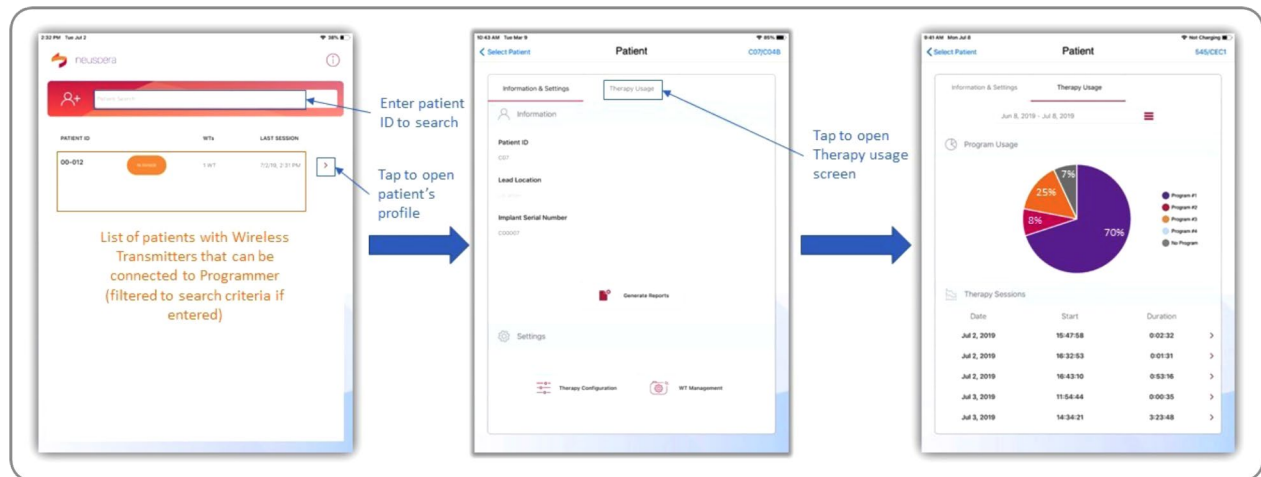


Figure 16. Retrieving a patient's profile.

Retrieving Patient Usage History

Assuming the Wireless Transmitter is within range, follow the steps outlined in Figure 17 to view the program usage history for that Wireless Transmitter.

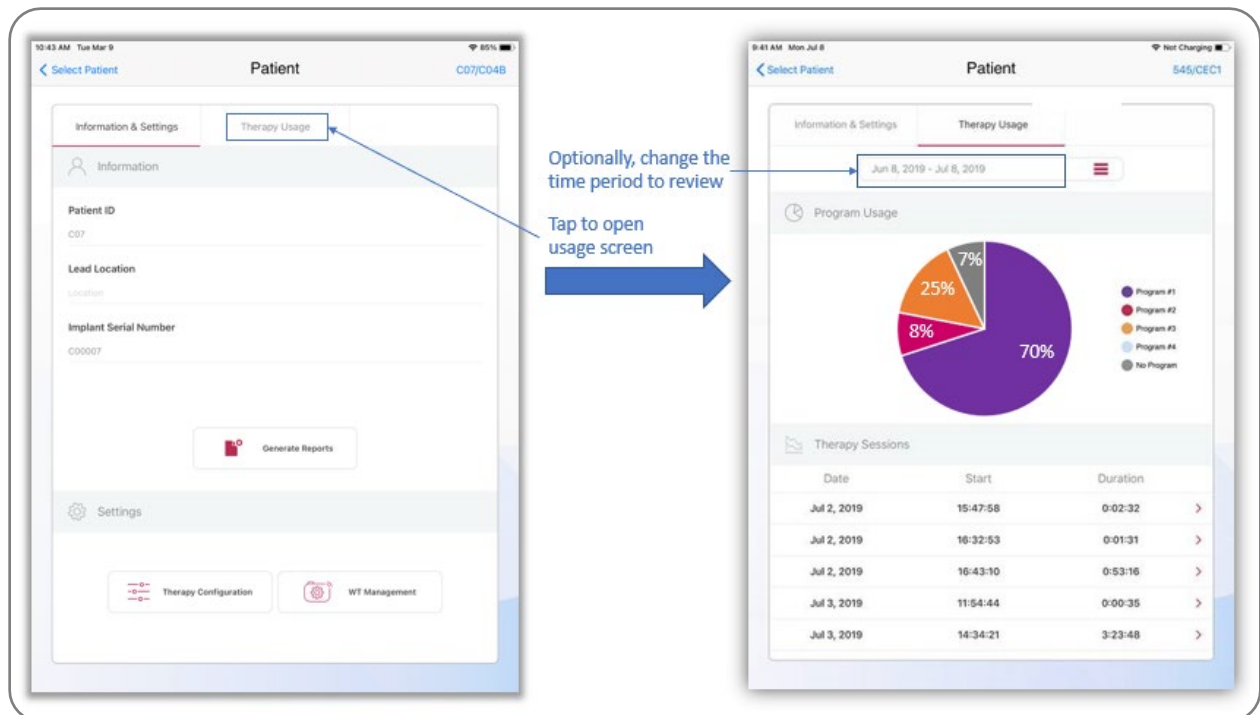


Figure 17. Navigating to and viewing patient's Therapy Usage history

Note: The Therapy Usage is for the Wireless Transmitter that is currently connected to the Clinician Programmer. If the patient has been using multiple Wireless Transmitters, the data for each Wireless Transmitter must be reviewed separately.

Adjusting Patient Stimulation Therapy Settings

If necessary to optimize the patient's therapy, stimulation settings and preset programs can be adjusted when the patient's Wireless Transmitter is within range of the Clinician Programmer. Refer to **"Therapy Configuration"** section of this manual.

Note: Each Wireless Transmitter must be separately connected to the Clinician Programmer and updated.

Note: To ensure that the Wireless Transmitter is properly updated with any adjustments made by the Clinician Programmer App, turn the Patient Controller App communication off from the Patient Controller App Info Screen (see **Figure 18**).

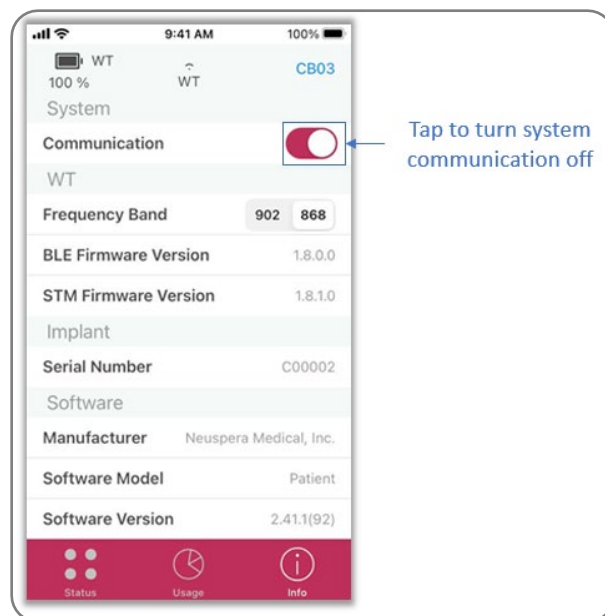


Figure 18. Patient Controller App Info screen.

Updating Apps or Wireless Transmitter Firmware

Occasionally, new versions of the Clinician Programmer or Patient Controller Apps or the Wireless Transmitter firmware will be released. Devices should be updated in a timely manner.

7. TROUBLESHOOTING

Common problems encountered with the Clinician Programmer App are listed below. If these do not solve the problem, contact Neuspera Medical. For additional problems that patients may experience with the Patient Controller App, please refer to the Patient Manual for the Neuspera SNM System.

Problem	Potential Cause	Recommended Resolution
Clinician Programmer cannot find Wireless Transmitter.	Wireless Transmitter battery is not charged.	Charge Wireless Transmitter.
	Clinician Programmer and Wireless Transmitter are too far away from each other.	Move Wireless Transmitter to within 1 meter (3 feet) of Clinician Programmer.
Clinician Programmer cannot connect to displayed Wireless Transmitter.	Wireless Transmitter battery is too low.	Charge Wireless Transmitter and retry connection.
Patient's Wireless Transmitter is listed under "Other Patient WTs".	Wireless Transmitter is associated to a different Neurostimulator serial number.	Confirm the correct Neurostimulator serial number is listed in the Patient's profile. If it is certain that the Patient's profile has the correct serial number, unassign the Wireless Transmitter by clicking on the red "-" unassign icon (see Figure 11) and then assign the Wireless Transmitter to the patient (see Figure 9). Note: When a Wireless Transmitter is reassigned, it must also be reassigned to the Patient Controller. On the Patient Controller's Info screen, "Delete all Connections" and then relink the Wireless Transmitter to the Patient Controller (see Figure 9).
Wireless Transmitter does not power an implanted stimulator.	Wireless Transmitter is too far from Neurostimulator (Wireless Transmitter must be directly over Neurostimulator).	Place Wireless Transmitter directly over Neurostimulator (wrap in sterile sleeve if necessary to maintain sterile field).
	Wireless Transmitter battery is too low (Wireless Transmitter will not connect to Neurostimulator if <10% battery).	Charge Wireless Transmitter to at least 10%.
	Wireless Transmitter is not assigned to Neurostimulator.	Confirm that the correct Neurostimulator serial number is in the patient profile (see Figure 8).
Clinician Programmer display doesn't turn on.	Clinician Programmer is turned off.	Turn Clinician Programmer on by pressing button on top edge of Clinician Programmer.

Problem	Potential Cause	Recommended Resolution
	Clinician Programmer battery is too low.	Charge device for at least 2 minutes and while still plugged in, turn Clinician Programmer on by pressing button on top edge of Clinician Programmer.
System is not responsive or not behaving as expected.	Possible EMI.	Move away from the interfering source (see EMI notes at the end of this manual).

7.1. Clinician Programmer App Messages and Resolutions

System Message	Cause	Resolution
Action Not Available Cannot change settings while Therapy is active	User tries to change stimulation settings while Wireless Transmitter is powering stimulator (only changes in amplitude are allowed while therapy is enabled).	Tap “OK” to close message. Turn off WT Power and then change settings. Turn WT Power back on after changes have been made.
Action Not Available Cannot change Neurostimulator Serial Number while WTs are assigned. Please unassign all WTs first.	User tries to change Neurostimulator serial number in patient profile after authenticating one or more WTs to the assigned serial number (authentication is specific to a Neurostimulator serial number so Neurostimulator serial number cannot be changed without reauthenticating the WT(s)).	Tap “OK” to close message. If Neurostimulator serial number really does need to be changed, navigate to the WT management screen and unassign all WTs (see Figure 11). Return to the Patient Profile screen to change Neurostimulator serial number and then reassign WTs.
Therapy Error Please flip over the WT to clear error.	Communication has been turned off or user tried to turn on WT Power after removing WT from charging pad without flipping the WT over.	Tap “OK” to close message. Go to Info page and turn on Communication. or If the WT was just removed from charging pad, flip over the WT to turn on WT Power.
WT Alert Battery level below 10%	Wireless Transmitter battery level is low.	Tap “OK” to close message. Charge Wireless Transmitter.
WT Alert WT temperature algorithm is non-functional	Wireless Transmitter control loop to monitor temperature has failed.	Tap “OK” to close message. Replace patient’s Wireless Transmitter and return faulty unit to Neuspera.

System Message	Cause	Resolution
Disconnected Connection to WT lost	Wireless Transmitter completely drained, turned off due to contact with a magnet, or moved out of range.	Ensure Wireless Transmitter is not near a magnet, is charged, and within range of the Clinician Programmer. If the issue continues, close the Clinician Programmer App, after a few minutes, restart Clinician Programmer App and try again.
<u>Retrieval Failure</u> Log file retrieval encountered an error. Data shown may not have been updated.	Communication between Clinician Programmer App and Wireless Transmitter interrupted.	Tap "OK" to close message. Ensure Clinician Programmer App is connected to the Wireless Transmitter. Switch to any other screen and then switch back to the Program Usage screen to update data.

8. TECHNICAL INFORMATION

8.1. System Physical and Performance Details

8.1.1. Neurostimulator

The implantable part of the Neuspera SNM System is a device with a timed stimulator connected to four programmable electrodes. The Neurostimulator is wirelessly powered by Neuspera's mid-field powering technology. The Neurostimulator only functions when it receives power from the patient's authenticated Wireless Transmitter. A patient's Neurostimulator cannot be powered by another patient's Wireless Transmitter.

The Neuspera Neurostimulator is compatible with the following stimulation parameters:

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

8.1.2. Wireless Transmitter (WT)

The Wireless Transmitter contains two antennae. One antenna connects to the Neurostimulator to transmit RF power and communication. The other antenna connects to the Clinician Programmer and Patient Controller Apps via Bluetooth® technology. The Wireless Transmitter is water resistant for daily cleaning. The Wireless Transmitter contains a battery and is wirelessly recharged using a Qi charging pad. The Wireless Transmitter can switch the frequency bands (managed by the Clinician Programmer or Patient Controller Apps) used to transmit power to the Neurostimulator for international traveling. A patient's Wireless Transmitter can only connect to that patient's Neurostimulator and Patient Controller and their clinician's Clinician Programmer.

The technical specification for the Wireless Transmitter is as follows:

Battery capacity	≥2000mAh
Battery capacity (therapy time)	≥2 hours (will vary with RF power control settings)
Time for full recharge	≤5 hours
Maximum operating surface temperature	<60°C (140°F)
Frequency range (powering)*	902-928 (ISM compliant band)
Frequency range (Bluetooth)	2.4-2.5GHz
Water resistance	IP25 (Protected from touch by fingers and objects greater than 12 millimeters. Protected from low pressure water jets from any direction)

8.1.3. Wireless Transmitter Charging Pad (CHP-5 or equivalent)

The Wireless Transmitter Charging Pad is an off-the-shelf Qi charging pad.

8.1.4. Clinician Programmer and Patient Controller

The Clinician Programmer and Patient Controller are Bluetooth-enabled devices configured to run only the Neuspera Clinician Programmer and Patient Controller Apps, respectively. These devices should not be connected to the internet other than to access the secure server hosting the Neuspera Apps.

8.1.5. Undergarment

The Neuspera Undergarment is designed to hold and maintain the Wireless Transmitter (WT) above the implanted Neurostimulator for delivery of therapy. The specially designed pocket will also pad and insulate the Wireless Transmitter against the body. The Undergarment is intended to be worn under general clothing (i.e. pants, shirts, and jackets) and over undergarments. It is also compatible with pads and diapers. The Undergarment is available in sizes from extra-small to XXX-large.

Instruct patients that for proper hygiene, it is recommended that 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.

8.1.6. Operating, Storage, and Temperature Conditions

The Wireless Transmitter and Clinician Programmer 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 Range
Wireless Transmitter	5°C to 35°C (41°F to 95°F)*	-25°C to 55°C (-13°F to 131°F)**
Clinician Programmer	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 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).

8.1.7. Service Life

The estimated service life of the components of the Neuspera System are 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

8.2. Disposal Guidance

- Follow local facility practices and policies for the return and disposal of tools as appropriate.
- After completion of implantation procedures, return any Neurostimulators that were not successfully implanted to Neuspera. To allow for device analysis, do not autoclave the devices or expose to ultrasonic cleaners.
- After explanting the Neurostimulator (e.g., replacement, cessation of therapy, or post-mortem), return the explanted Neurostimulator, Wireless Transmitter(s), and Patient Controller to Neuspera. To allow for device analysis, do not attempt to clean or sterilize the devices.

Caution:

- Follow appropriate biohazard material handling protocols for all explanted components or components coming into contact with bodily fluids. Only return such components to Neuspera in the appropriate packaging supplied by Neuspera.
- Do not reuse any implantable device or implantable accessory after exposure to body tissues or fluids because the sterility and functionality of the component cannot be guaranteed.

External Components

The Wireless Transmitter and Patient Controller contain lithium ion batteries and must be disposed of according to local law.

There are no special procedures to dispose of the Undergarment.

8.3. Compliance

Neurostimulator	ISO 14708-3 (active implantable devices – neurostimulators) IEC 60601-1 ISO 10993 (permanent tissue contact)
Wireless Transmitter	IEC 60601-1 (Type BF Applied Part) IEC 60601-1-2 (Group 2, Class B - Immunity for the home healthcare environment) IEC 60601-1-6 IEC 60601-1-11 IEC 62133-2 (battery)
Clinician Programmer and Patient Controller*	IEC 60950-1
Charging Pad*	FCC Part 15 Subpart C 15.209

**The hardware for the Clinician Programmer, Patient Controller, and the Charging Pad are off-the-shelf consumer-grade information technology equipment and are being used in compliance with their intended use. Therefore, this hardware was not evaluated for compliance with IEC/ISO 60601-1 and biocompatibility (ISO 10993) when used according to these instructions.*

8.4. Wireless Technology Information**8.4.1. Quality of Service**

The Neuspera SNM System uses wireless communication between the Neurostimulator and Wireless Transmitter, and between the Wireless Transmitter and Apps.

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 belt or 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.

8.4.2. System Security

After the Neurostimulator is implanted, the Wireless Transmitter will be uniquely paired to the Neurostimulator and the Clinician Programmer and Patient Controller Apps.

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.

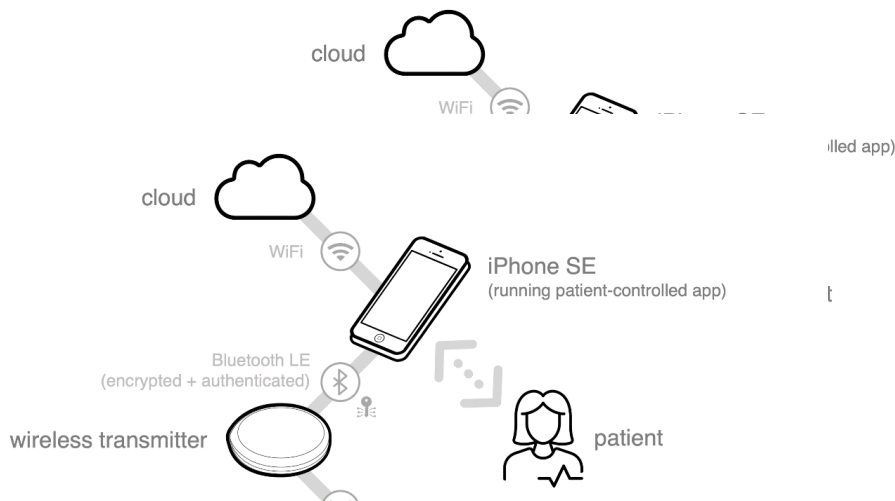


Figure 19. Schematic of authenticated connections/communications

8.4.3. 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 a patient's Neurostimulator to a patient's Wireless Transmitter and the Wireless Transmitter to the Clinician Programmer and Patient Controller App. The Wireless Transmitter will only communicate with an authenticated paired App. 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 implantable (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 Clinician Programmer and Patient Controller.

Authentication

A strong cryptographic challenge-response mechanism using symmetric cryptography has been implemented to authenticate each party. The Patient Controller and Clinician Programmer will each pair through a different workflow of authorization. Patient Controllers 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 Clinician Programmer and 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 firmware or the Clinician Programmer App, a notification is sent to the clinician about the availability along with a link to download. The clinician can then download the firmware or the App. No other action is needed by the clinician.

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 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").

Decommissioning

Data may be removed from the Clinician Programmer and 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 charging pad for several sessions such that all data is overwritten.

8.5. MRI Safety Information

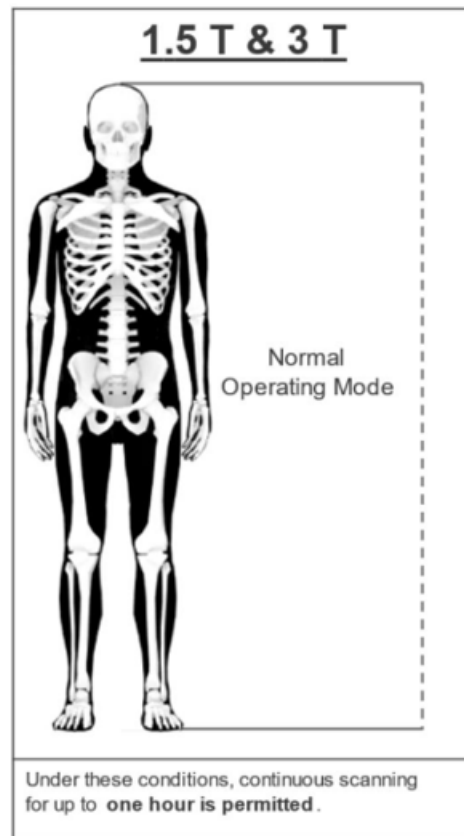
Non-clinical testing has demonstrated that the Neuspera SNM System Neurostimulator is MR Conditional. The neurostimulator does **not** need to be programmed to a special mode to undergo an MRI.

Remove all external components before scanning. The clinician and patient programmers, and accessory components including the intraoperative test kit, intraoperative external stimulator, guidewires, foramen needles, pre-dilators, delivery assembly 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. If information about a specific parameter is not included, there are no conditions associated with that parameter.

A patient 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



8.6. 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 | • Defibrillators |
| • Power substations | • Radiation therapy |
| • MR imagers | • Arc welders |
| • Cardiac devices | • Theft detections/screening devices |
| • Strong permanent magnets | • Plasma cutters |

Counsel patients to 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.

8.6.1. EMC-Related Precautions

- The Wireless Transmitter should not be used during any electromagnetic medical investigation or treatment.
- Diathermy (shortwave, microwave, or therapeutic ultrasound) and radiofrequency ablation in the vicinity of the Neurostimulator should not be used because these procedures have not been evaluated.
 - Therapeutic ultrasound should not be used in the area of the Neurostimulator as the device can inadvertently concentrate the ultrasound field and cause harm.
 - Therapeutic ionizing radiation can damage the electrical components of the Neurostimulator and any damage may not be immediately detectable.
- The Neuspera SNM 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 SNM System has not been tested for compatibility with cardiac defibrillation. Check the performance of the Neurostimulator after defibrillation.
- 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 – Patients 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 ○ 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)
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Note: If patients suspect that equipment is interfering with Wireless Transmitter 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.

- Laser procedures – Remove the Wireless Transmitter. Keep the laser directed away from the neurostimulation system.
- 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.
- Transcutaneous electrical nerve stimulation (TENS) – Do not place TENS electrodes so that the TENS current passes over any part of the Neurostimulator. If patients feel that the TENS may be interfering with the implanted Neurostimulator, they should discontinue using the TENS until they talk with their clinician.

8.6.2. 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.

8.6.3. 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.

8.6.4. 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 23. Guidance and manufacturer's declaration – electromagnetic emissions

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF Emissions 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 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 24. 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 ±2 kV, ±4 kV, ±8 kV and ±15 kV air	±8 kV contact ±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 80 MHz to 2.7 GHz Refer to table 3 for wireless proximity RF field compliance levels	10 V/m <u>80 MHz to 2.7 GHz</u> Refer to table 3 for wireless proximity RF field compliance levels	
Radiated Fields in Close Proximity IEC 61000-4-39	8 A/m CW 65 A/m, Pulse modulation 2.1 kHz 7.5 A/m, Pulse modulation 50 kHz	8 A/m CW 65 A/m, Pulse modulation 2.1 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 25. 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 FRS 460	FM $\pm$ 5kHz deviation 1kHz Sine Wave	28	28
710 745 780	704 - 787	LTE Band 13 & 17	Pulse Modulation 217 Hz	9	9
810 870 930	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse Modulation 18Hz	28	28
1720 1845 1970	1700-1990	GSM 1800 CDMA 1900 DECT LTE Band 1,3,4,25, UMTS	Pulse Modulation 217 Hz	28	28
2450	2400-2570	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse Modulation 217 Hz	28	28
5240 5500 5785	5100 -5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	9	9



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Neuspera Trial System

Clinician Manual

R_x only

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

Symbol	Description
	Catalog number
	Batch code
	Serial number
	Quantity
	Wireless transmitter identification number
	Sterilized using ethylene oxide
	Manufacturer
	Date of manufacture
	Use before date
	Refer to instruction manual
	Consult Instructions for Use
	Do not use if package is damaged
	Do not re-use
	Do not re-sterilize
	Magnetic Resonance (MR) Unsafe
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Keep away from sunlight
	Keep dry
	Protected from touch by fingers and objects greater than 12 millimeters. Protected from low pressure water jets from any direction.

Symbol	Description
	Protected from limited dust ingress. Protected from high pressure water jets from any direction.
	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	
EM / EMI	electromagnetic / electromagnetic interference
IT	information technology
mA / μ A	milliamperes / microamperes
MR / MRI	magnetic resonance / magnetic resonance imaging
UUI	urinary urge incontinence
RF / RFID	radiofrequency / radiofrequency identification
SAR	specific absorption rate (measure of wireless power absorbed by the body)
SNS	sacral nerve stimulation
USB	universal serial bus
V	volts
WT	wireless transmitter

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1 INTRODUCTION

This manual provides information on the trialing system and procedure for the Neuspera Sacral Neuromodulation (SNM) System.

2 SYSTEM DESCRIPTION AND OPERATING PRINCIPLE

The Neuspera Trial System is intended for the evaluation of SNM Therapy, also referred to as “test stimulation” or “therapy evaluation,” prior to permanent implant of the Neuspera SNM Permanent System. See **Figure 1** for images of the system components, and **Figure 2** for placement of the Trial System on the patient’s back.

Device should only be placed by physicians formally trained in placement of sacral neuromodulation devices.

The Trial Lead is a temporary lead with a single electrode that allows the electrical pulses from the External Stimulator to be delivered to the sacral nerve. It is designed to be implanted percutaneously under a local anesthetic.

The Trial Lead is connected to the External Stimulator, an externally worn stimulator. Electrical pulses generated by the External Stimulator stimulate the sacral nerve to test a patient’s response to SNM therapy. The Trial Lead exits the skin and is connected to the External Stimulator, which is held in place with adhesives. A second Trial Lead may be placed on the contralateral side and connected to the same External Stimulator.

The trial stimulation occurs in two (2) phases. In the first phase, the clinician locates the appropriate sacral nerve root of the patient using a Foramen Needle connected to the External Stimulator. Accurate placement of the needle tip is verified by observation of the appropriate patient motor responses and sensory responses, such as contraction of the levator ani muscles, and flexion of the greater toe. Once the optimum sacral nerve stimulation location has been identified, a Trial Lead is percutaneously placed at the sacral nerve site, and an External Stimulator is connected. Appropriate lead placement is again verified by observing the appropriate patient responses. A second Trial Lead may be placed on the contralateral side in the same manner, to determine which side leads to the best improvement in the patient’s UUI symptoms. Once electrode placement is confirmed, the patient completes the second phase of the trial stimulation – continuous stimulation (24 hours a day) to determine if therapy improves patient’s symptoms, typically conducted over three (3) to seven (7) days.

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

No technical maintenance is required on any of the Neuspera System components.

This manual covers the following products:

- Trial Lead Kit
 - Trial Lead with Stylet (EO sterilized)
 - Foramen Needles (3.5") (EO sterilized)
- Extra Trial Lead
 - Trial Lead with Stylet (EO sterilized)
- Procedural Accessories Kit
 - Surgical marker and ruler (EO sterilized)
 - Surgical drape (EO sterilized)
 - Transparent adhesive medical dressing (3x) (non-sterile)
 - Gauze (EO sterilized)
 - Adhesive remover pad (non-sterile)
 - Alcohol prep pad (EO sterilized)
 - Surgical tray (EO sterilized)
 - Hypodermic needle (x2) (EO sterilized)
 - Paper drape (EO sterilized)
 - Gauze sponge (2x) (EO sterilized)
 - Syringe (x3) (EO sterilized)
 - Iodine Prep Solution (non-sterile)
 - Blunt needle (EO sterilized)
 - Sponge Stick (x3) (EO sterilized)
- External Nerve Stimulator Kit
 - External Stimulator (non-sterile)
 - Ground pads, Trial (2x) (non-sterile)
 - Intraoperative Cable (EO sterilized)
 - Ground pad, Intraoperative (2x) (non-sterile)
- Wireless Transmitter and Accessories (Charging Pad and Magnet) (non-sterile)
- Clinician Programmer (non-sterile)
- Patient Controller (non-sterile)

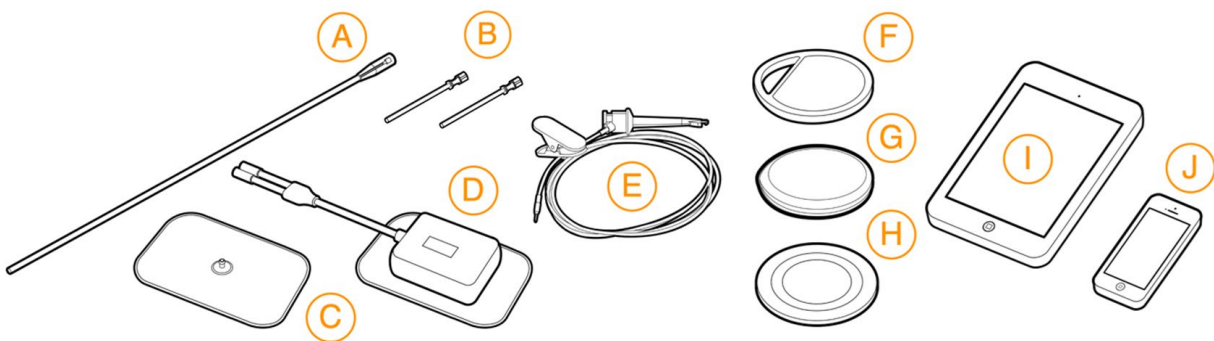


Figure 1. Neuspere Trial System Components.

A. Trial Lead with Stylet; B. 3.5" Foramen Needle (protective cap not shown); C. Intraoperative Ground Pad; D. External Stimulator with Ground Pad; E. Intraoperative Cable; F. Magnet; G. Wireless Transmitter (WT); H. Charging Pad; I. Clinician Programmer; J. Patient Controller. Procedural Accessories not shown.

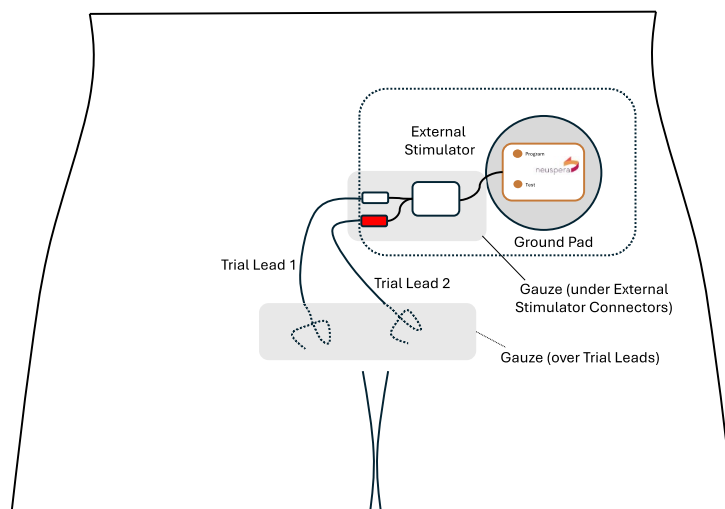


Figure 2. Placement of Neuspera Trial System.

2.1 Trial Lead with Stylet

The Trial Lead is a temporary 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 in a percutaneous procedure. The Trial Lead is 34 cm long and has a diameter of 0.84 mm. The contact is 7.4 mm in length. The Trial Lead is introduced through the sacral foramina to allow the electrode at its tip to stimulate the sacral nerve root; the remainder of the Trial Lead exits the skin to be connected to the External Stimulator.

2.2 Foramen Needles

The Foramen Needle is used to locate the sacral foramen, to test and stimulate the sacral nerve root, and to introduce and position the Trial Lead within the sacral foramen.

2.3 Intraoperative Ground Pad

The Intraoperative Ground Pad is used in conjunction with the Foramen Needle and External Stimulator to perform functional mapping of the sacral nerve to identify the placement location for the Trial Lead. The Intraoperative Ground Pad serves as the 0 electrode as well as a mechanism to secure the external stimulator in place.

2.4 External Stimulator with Trial Ground Pad

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 an adhesive surgical dressing to ensure that it is secured and protected during the stimulation trial. The External Stimulator will continue to stimulate as programmed as long as the Orange U-Clip remains in the closed (flush) position.

2.5 Intraoperative Cable

The Intraoperative Cable is used to connect the External Stimulator and the Foramen Needle or Trial Lead in order to perform intraoperative testing.

2.6 Wireless Transmitter (WT) and Accessories (Charging Pad and Magnet)

For the Trial System, the Wireless Transmitter is used as a conduit for the Patient Controller or Clinician Programmer to communicate with the External Stimulator.

The Charging Pad is used to recharge the Wireless Transmitter, and the Magnet is used to reset the Wireless Transmitter or turn it off and conserve its stored battery power when it is not in use or being charged.

2.7 Clinician Programmer and Patient Controller

The Clinician Programmer and Patient Controller are Bluetooth-enabled devices configured to run only the Neuspera Clinician Programmer and Patient Controller Apps, respectively. The Clinician Programmer is used by the clinician to program the patient's External Stimulator via the Wireless Transmitter. The Patient Controller is used by the patient to turn the stimulation on/off, adjust stimulation amplitude, and select pre-configured stimulation programs via the Wireless Transmitter.

3 INTENDED USE

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

4 PRESCRIPTION AND SAFETY INFORMATION

The Neuspera Trial System is for use with a prescription only.

4.1 Contraindications

- Patients with sacral depth measured from skin to the S3 foramen greater than 10 cm as confirmed by imaging
- Patients who have not demonstrated an appropriate 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 lower urinary tract obstructions that leads to significant obstructive symptoms or pathology

After implantation of the Neurostimulator, the following contradictions apply:

- Electrical treatments where the conducted current is induced into the body from an external source in the area of the External Stimulator (this may permanently damage the External Stimulator)
- Medical treatments or procedures utilizing effects caused by electric fields (such as diathermy)

4.2 Warnings

Do not detach or disassemble devices, or use accessories not described in this manual. The system may not function according to specification under these conditions.

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

Implant fracture or migration may occur. Patients should be monitored for potential fracture or migrations if they have any loss of stimulation.

Inform patients of the following warnings:

- Wearing the Wireless Transmitter against your skin may result in discomfort, irritation, or a burn.
- Do not use the Wireless Transmitter in situations where the temperature is very hot (above 35°C or 95°F) or in conditions where there is limited air circulation (such as under a blanket, heavy clothing, or in a heavily padded chair). Doing so could result in the Wireless Transmitter overheating. Burns or other injury could result.
- Do not use the Wireless Transmitter if you are unable to feel that the device is getting too hot, such as while sleeping. Burns or other injuries could result.

Electromagnetic Interference (EMI) from various sources may damage the device, interfere with device operation, or cause harm to the patient. Please consider the following:

- Defibrillation or Cardioversion
 - When a patient is in ventricular or atrial fibrillation, the first consideration is patient survival. External defibrillation or cardioversion can damage the Trial System and cause induced currents in the lead or other system components that can injure the patient. Minimize the current flowing through the lead by following these guidelines:
 - Position defibrillation paddles as far from the lead as possible.
 - Position defibrillation paddles perpendicular to the lead.
 - Use the lowest clinically appropriate energy (joules) output (watt seconds).
 - After defibrillation, confirm the Trial System is functioning as expected.
- Electrocautery
 - The Trial System should be removed prior to any procedure that involves electrocautery. If electrocautery is used near an implantable device or contacts a device or insertion-needle, the following effects may occur:
 - The tissue surrounding the device may be damaged.
 - The Trial System may be damaged, or stimulation may be temporarily suppressed or increased.
 - If electrocautery is necessary without complete removal of the device, follow these precautions:
 - Before using electrocautery, remove the Wireless Transmitter and External Stimulator.
 - After electrocautery, confirm 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 for patients that are undergoing a stimulation trial. Patients should wait until after their trial procedure is done and the Trial System is removed before having these procedures.
- Radiofrequency (RF) or microwave ablation – 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. Patients 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) 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. Patients should wait until after their 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 may not be visible.

- Theft detectors found in retail stores, public libraries, etc., and security screening devices found in airports, government buildings, etc., may occasionally cause a momentary change in stimulation. When passing through these devices while undergoing a trial procedure with the Neuspera Trial System, some patients may perceive a momentary change in stimulation when they pass through these devices. It is also possible that patients, especially those that have low stimulation levels, may feel a momentary change in stimulation when they pass through these devices.
- When approaching these devices, patients should do the following:
 - If possible, instruct patients to request to bypass these devices. Security personnel may use a handheld security wand but patients should ask the security personnel not to hold the security wand over the Trial System any longer than is absolutely necessary. Patients may wish to ask for another form of personal search.
 - If patients must pass through the theft detector or security screening device, they should use their Patient Controller and Wireless Transmitter to turn off their External Stimulator.
 - If two security gates are present, they should walk through the middle at a normal pace, keeping as far from each gate as possible.
 - If one gate is present, they should walk as far from it as possible.
 - Proceed through the security device at a normal pace. Patients should not lean or linger on the screening device.
 - After patients pass through the security device, they should re-enable therapy.

4.3 Precautions

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

- Prior to use, clinicians should be trained on the implantation procedure and use of the Neuspera Trial System.
 - Implanting clinicians should be trained on sacral nerve stimulation (SNS), the trialing procedure, and use of the Neuspera Trial System. A formal training program, including both a didactic session and a hands-on training lab, will be provided for the Neuspera SNM System; clinicians will be required to pass a formal knowledge assessment prior to implanting the device.
 - A Neuspera Field Clinical Engineer (FCE) is required to be present at each implantation procedure. Please contact your local sales representative or call (888) 846-8332 or email Physicianhelp@neuspera.com to ensure an FCE will be present at the procedure.

- Prescribing clinicians should be experienced in the diagnosis and treatment of lower urinary tract symptoms and should be trained on the use of the Neuspera SNM System.
- The Neuspera Trial Lead Kit, Extra Trial Lead, Procedural Accessories Kit, and External Nerve Stimulator Kit are single use only. Reuse of these devices may result in patient harm including, but not limited to, systemic infection.
- The implantation procedure may use fluoroscopy, and it is recommended that the fluoroscope documentation be consulted for applicable warnings, contraindications, etc.
- Do not use the Wireless Transmitter, Patient Controller, charging pad, or charging cables if they are damaged. Using damaged devices and cables may result in fire, electrical shock, injury, or additional damage.
- Ensure the Wireless Transmitter is not punctured or damaged to prevent battery leakage.
- If rash or other adverse skin reactions occur, instruct the patient to stop using the device, and monitor the skin.
- The Wireless Transmitter is not intended for direct skin contact.
- The patient should turn off stimulation or remove the Wireless Transmitter if any of the components becomes uncomfortably hot.
- The Wireless Transmitter may heat up while charging. The WT should not be worn while it is charging since it heats up during charging. The Wireless Transmitter cannot communicate while charging.
- The External Stimulator should not be placed in areas with broken or blistered skin or with poor circulation.
- The Wireless Transmitter, Patient Controller, and Clinician Programmer should not be brought into any room with an MR machine. Doing so could cause them to be drawn into the bore of the MRI and cause serious injury to the patient.
- The Neuspera Trial Lead and External Stimulator are MR Unsafe.
- The safety and performance of the Neuspera Trial System has not been evaluated for use in the following:
 - Patients with BMI > 40,
 - Pregnant women,
 - Pediatric patients,
 - Bilateral stimulation with the permanent Neuspera SNM System (bilateral stimulation may be used with Trial System),
 - Patients with neurologic cause of OAB such as multiple sclerosis, diabetes, or Parkinson's disease.
- The Neuspera Trial 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 Trial System has not been tested for compatibility with cardiac defibrillation.
- 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.

4.3.1 Patient Activities

During the trial procedure, patients should 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.

Patients 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 themselves 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.

Patients should use caution with normal activities such as getting dressed and putting on shoes. Postural changes, and other activities may result in the patient perceiving an increase in stimulation which may be uncomfortable. Some patients have described this as a jolting or shocking sensation.

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

Patients should turn the test stimulator OFF while driving (it may remain on while the patient is 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 the patient were to be driving at the time, the sudden discomfort or pain could cause the patient to lose control of the vehicle resulting in significant injury or death.

4.3.2 Component Manipulation

Patients should 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.

Patients should 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.

4.4 Adverse Events

Below is a list of the potential adverse effects 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)
- 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
- Implant fracture/failure
- Implant migration
- 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, hemorrhage, and/or hematoma
- Nerve injury (including numbness)
- Technical device malfunction
- Transient electric shock or tingling
- Vulvovaginal pain or pelvic pain
- Unintended nerve activation

5 SUMMARY OF CLINICAL EVALUATIONS

5.1 Introduction

Neuspera conducted a clinical study (IDE number G190064) to determine the safety and effectiveness of the Neuspera Sacral Neuromodulation (SNM) System for the treatment of urinary urge incontinence (UUI). The study design and data are summarized below.

5.2 Study Design

The SANS-UUI pivotal study (“Neuspera pivotal study”) was a prospective, multi-center, single-arm study to evaluate the safety and effectiveness of the Neuspera SNM System in the treatment of UUI. The study included patients with UUI who failed, could not tolerate, or were not a candidate for more conservative treatments, and 128 patients were implanted with the Neuspera SNM System. The SANS-UUI pivotal study was conducted in 29 clinical sites in the U.S. and 2 sites in Europe. The study evaluates the safety and effectiveness of the Neuspera SNM System after all subjects reached their 6-month visit. Additional data was collected beyond 6 months, including secondary endpoints at 12 months; see Figures 1 and 2 for the patient follow-up timepoints. The primary effectiveness endpoint is defined as the percentage of all patients with an attempted implant who experience an improvement in their UUI symptoms of at least 50% or more (“therapy responders”). A therapy responder is defined as experiencing $\geq 50\%$ reduction in the number of UUI episodes at 6 months after implant, compared to number of UUI episodes at baseline. The primary safety endpoint is defined as the number of device-related SAEs through the 6-month post-implant visit.

Table 1 shows the inclusion and exclusion criteria for the study.

Table 1: Inclusion and Exclusion Criteria

General inclusion criteria:	
1.	Is willing and able to understand and has voluntarily signed and dated the current approved informed consent.
2.	Is male or female 22 years of age or older.
3.	Has a Body Mass Index (BMI) greater than or equal to 18 and less than or equal to 40 kg/m ² .
4.	Is a good surgical candidate and is capable of participating in all testing and follow-up clinic visits associated with this clinical study and is capable of independently using the system components as described in the Patient Manual.
5.	Is ambulatory and able to use toilet without assistance.

6. Has a diagnosis of UUI for greater than or equal to 6 months prior to the screening baseline visit date. 7. Has typical residual bladder volume <150 cc tested within 6 months prior to the screening baseline visit date or is willing to have a test at screening baseline visit. 8. Has urodynamic testing (uroflowmetry, cystometry, and pressure flow) completed within 6 months prior to the screening baseline visit date or is willing to have testing at the screening baseline visit. 9. Has cystoscopy testing completed within 6 months prior to the screening baseline visit date or is willing to have a test at the screening baseline visit. 10. Has failed or was not a candidate for more conservative treatment (e.g., pelvic floor exercise, biofeedback, behavioral modification) 11. Has failed, could not tolerate (stopped taking medication due to lack of efficacy or intolerable side effects), or not a good candidate for (as determined by treating physician) at least one (1) antimuscarinic or β_3 adrenoceptor agonist medication. 12. Is willing and able to washout (at least five half-lives) from OAB medications for a period determined appropriate based on type of OAB medication prior to the baseline bladder diary and remain off OAB medications through the 12-month follow-up visit. 13. Has appropriate sacral anatomy as determined by sponsor's and investigator's analysis of radiographic imaging. (The distance from the surface of the skin in the prone and seated position to the bone edge of the S3 foramen must be within the capabilities of the system).
Baseline Bladder Diary Inclusion Criteria:
14. Has a diagnosis of UUI with at least 4 UUI episodes on a 72-hour diary, and minimum of one (1) UUI episode per 24-hour period.
General exclusion criteria:
1. Has a hemoglobin A1c of >8%, or has diabetes mellitus with glucosuria. 2. Has diabetic neuropathy. 3. Has interstitial cystitis or bladder pain syndrome as defined by either American Urological Association (AUA) or European Association of Urology (EAU) guidelines, chronic pelvic pain, or recurrent symptomatic urinary tract infections. 4. Has skin, orthopedic, neurological, or hematological (bleeding disorder) or anatomical limitations that could prevent successful placement of the neurostimulator. 5. Has broken, blistered skin or compromised circulation in the area of the neurostimulator implant. 6. Has neurogenic bladder dysfunction such as traumatic or atraumatic myelopathy, multiple sclerosis, Parkinsonism, or history of cerebrovascular accident. 7. Has documented urinary retention within 6 months prior to the screening baseline visit date. 8. Has clinically significant bladder outlet obstruction. 9. Is currently undergoing or has previously undergone pelvic irradiation. 10. Is a subject with a mechanical obstruction such as benign prostatic hypertrophy, urethral stricture, or cancer. 11. Has current grade 3 or 4 pelvic organ prolapse including cystocele, rectocele, enterocele, procidentia, or vaginal vault prolapse.

12. Has symptomatic urinary tract infection (UTI); the subject may be considered for study enrollment if the subject is symptom-free after a full course of treatment prior to beginning the baseline bladder diary. If an asymptomatic bacteriuria is detected during the urinalysis performed at screening, a subject may be enrolled without a waiting period relative to UTI treatment.
13. Has primary stress incontinence or mixed incontinence where the stress component predominates or has been treated surgically for stress urinary incontinence within 6 months prior to the screening baseline visit date.
14. Has received tibial nerve stimulation (TNS) in the past 3 months for the treatment of overactive bladder or unwilling to stay off TNS therapy for 12-month period following implant.
15. Has received treatment of urinary symptoms with any botulinum neurotoxin type-A (BoNT-A) agent in the past 12 months; (e.g. onabotulinumtoxinA, Botox®, abobotulinumtoxinA, Dysport®, IncobotulinumtoxinA, Xeomin®).
16. Is a woman who is pregnant or planning to become pregnant during this clinical study or is a woman of child-bearing potential who is not using a medically acceptable method of birth control. Women of child-bearing potential must undergo a pregnancy test, with clear negative result.
17. Has active substance abuse, including alcohol.
18. Has a known hypersensitivity or contraindication to procedural or post-procedural medications which cannot be adequately managed medically.
19. Has a known hypersensitivity to Neuspera's SNS System device components.
20. Has previously failed SNS therapy.
21. Has active implantable medical devices such as neurostimulators, drug pumps, pacemakers, or internal defibrillators since compatibility has not been assessed.
22. Has known needs for diathermy (shortwave, microwave, or therapeutic ultrasound), and radiofrequency ablation in the vicinity of the neurostimulator since these procedures have not been evaluated.
23. Has a known need for therapeutic ultrasound in the area of the sacral nerve neurostimulator as the device can inadvertently concentrate the ultrasound field and cause harm.
24. Has a known need for therapeutic ionizing radiation as can damage the electrical components of the sacral nerve stimulator and any damage may not be immediately detectable.
25. Has plans to enroll or is currently enrolled in another investigational device or drug trial during his/her participation in this study.
26. The investigator is unable to elicit an appropriate motor response in the subject during the intra-operative testing of the implant procedure.

5.2.1 Patient Disposition

34 sites were activated, and 31 sites enrolled 242 patients. At 25 sites, 130 patients had implants attempted, and 128 patients were successfully implanted. See **Figure 3** for the patient disposition at the time of database lock for the 12-month analysis. At the time of the 12-month database lock, the reasons for withdrawal of enrolled subjects are summarized as follows: patients who did not meet

eligibility criteria, 33.1% (80/242); withdrew consent, 10.3% (25/242); patients not satisfied with therapy, 3.7% (9/242); patients lost to follow-up, 2.5% (6/242); patients withdrawn by investigator, 1.7% (4/242); patients withdrawn as the sites were terminated by the sponsor, 1.7% (5/242); patients withdrawn due to adverse event, 1.2% (3/242); implant attempted but not completed, 0.8% (2/242); patient deceased, 0.4% (1/242); and were withdrawn for other reasons, 2.9% (7/242).

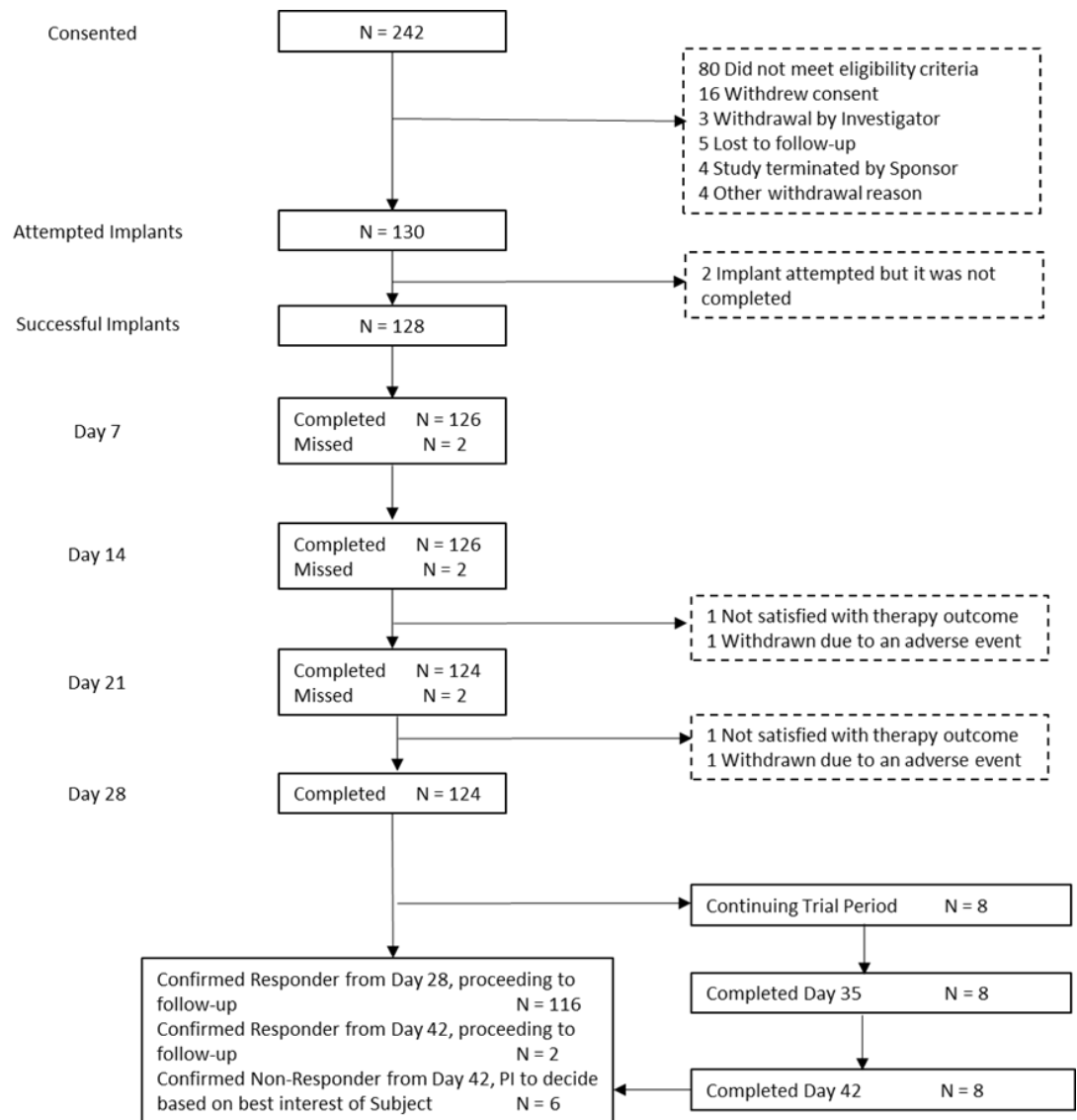


Figure 3: Patient Disposition – Post Implant Period

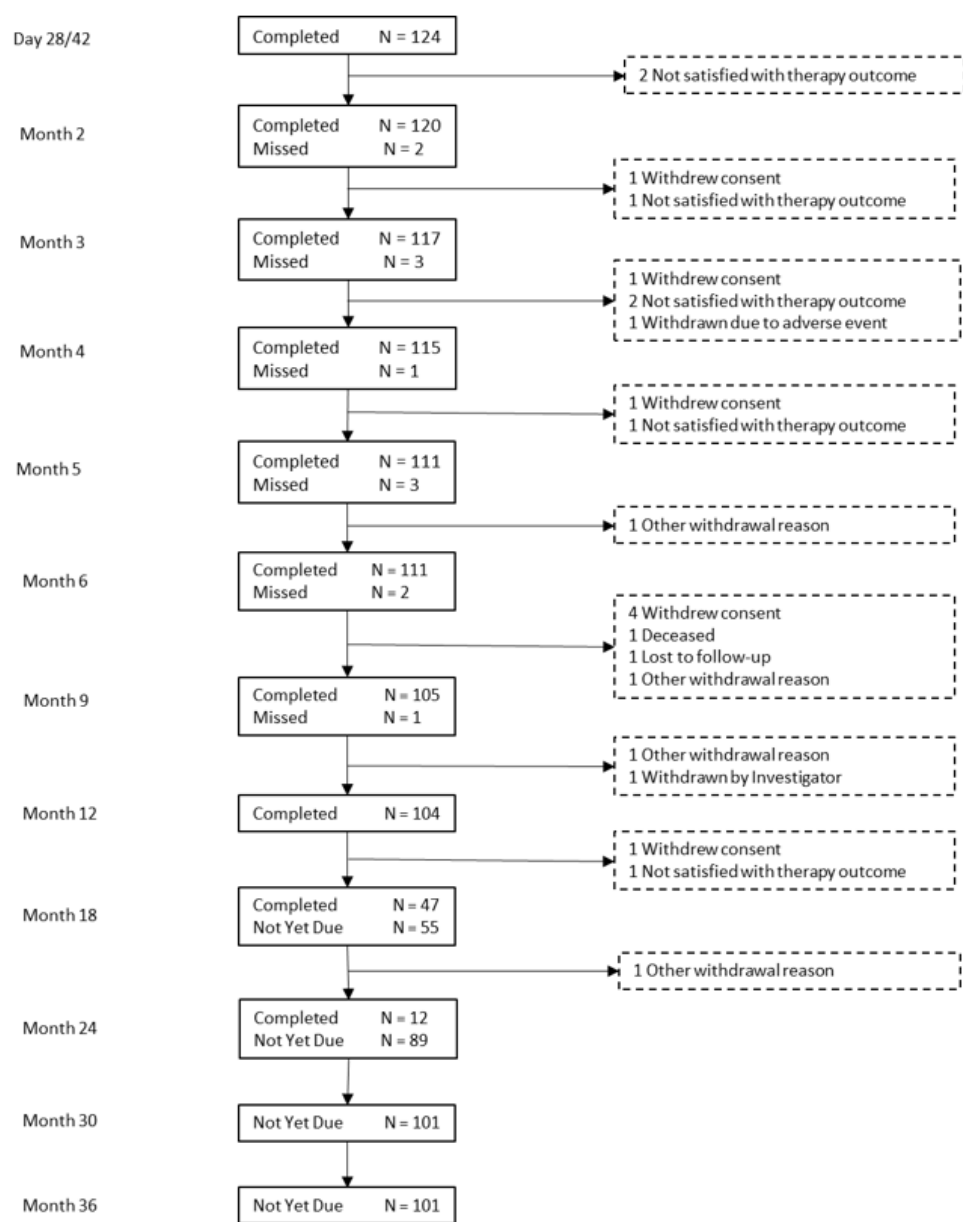


Figure 3: Patient Disposition – Post Implant Period (continued)

5.2.2 Analysis Sets

The analysis sets were pre-specified in the protocol as follows:

- **Intent-to-Treat (ITT) Analysis Set:** The ITT analysis set is defined as all patients who have signed informed consent.
- **Modified Intent-to-Treat (mITT) Analysis Set:** The modified Intent-to-Treat (mITT) Analysis Set is defined as all patients for whom an initial implant is attempted.

- **Implanted Analysis Set:** The Implanted analysis set is defined as all patients who are implanted with the Neuspera SNS system.
- **Responder Analysis Set:** The Responder analysis set is defined as patients who are implanted with the system and are defined as responders at the Day 28 or Day 42 clinic visit post-implant.
- **Per Protocol (PP) Analysis Set:** The Per Protocol analysis set is defined as implanted patients who have no protocol deviations that may significantly affect the primary endpoints. The determination of patients excluded from the Per Protocol analysis set was made prior to analysis.
- **Worst Case Analysis Set:** The Worst Case analysis set assumes that all patients with missing data were failures.

5.2.3 Patient Demographics and Baseline Characteristics

5.2.3.1 Demographics

Table 2 shows the baseline demographics of the mITT patients.

Table 2: 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)
Not Hispanic or Latino	120/130 (92.3)

5.2.3.2 Incontinence History

Table 3 presents the patients' incontinence history as reported at the baseline visit.

Table 3: 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	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.

5.2.3.3 UUI Treatment History

Patients in the mITT analysis set had a baseline of 4.5 ($\pm$ 2.5 SD) UUI episodes per day. See **Table 4** for the mITT patients categorized by severity of their UUI symptoms at baseline.

Table 4: 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 5 presents the patients' UUI treatment history as reported at baseline.

Table 5: 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 β 3 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)

5.2.4 Safety Results

Safety was demonstrated by a review of all Adverse Events (AEs). There were no device-related severe adverse events (SAEs) through the 12-month post-implant visit. There were a total of 338 adverse events in 108/130 (83.1%) patients, and 27 severe adverse events in 21/130 (16.2%) of patients in patients who had an attempted implant. One SAE was determined possibly related to the implant procedure. There were a total of 27 device-related events in 21 of 130 (16.2%) patients, and 21 procedure-related events in 19 of 130 patients (14.6%). Thirteen (13) events were definitely related to the device and one event definitely related to implant procedure.

There were 2 device fractures, 5 device migrations in 4 patients, 4 revisions, and 15 device explants at 6-months. At 12-months, there were a total of 5 device revisions and 21 explants. At 12 months, the number of device fractures and migrations did not change from 6 months. The majority of the migrations occurred within the first month of implant, and the fractures occurred on Day 26 and Day 63. However, one additional device fracture was seen after the 12-month data lock and was attributed to chiropractic manipulation. **Table 6** shows the fractures, migrations, and revisions that occurred through the 12-month datalock.

Table 6: Fractures, Migrations, Revisions, and Explants through 12 months post-implant

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

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

Table 7 shows the device-related adverse events, and **Table 8** shows the procedure-related adverse events through the 12-month post-implant visit.

Table 7. Device-Related Adverse Events through 12-months post-implant – mITT Analysis Set (N = 130)

	Events n	Patients n/N (%) ²
Total Device-Related Adverse Events¹	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 8: Procedure-Related Adverse Events through 12 months post-implant – mITT Analysis Set (N = 130)

	Events n	Patients n/N (%)²
Total Procedure-Related Adverse Events¹	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%)

¹As coded by the Clinical Events Committee chairperson.

² Exact 95% confidence Interval.

Table 9 shows device-related AEs as a function of time after implant through the 12-month visit database lock.

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

Device-Related AEs	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
Radicular pain			1				1
Urinary tract infection						1	1
Vulvovaginal pain		1					1

Table 10 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 10: 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
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

5.2.5 Effectiveness Result

5.2.5.1 Six-Months Results (Primary Endpoint)

For patients with an attempted implant (N=130), 82.9% of patients at Month 6 were responders ($\geq 50\%$ reduction from baseline in UIIs per day). The study met the 50% performance goal at 6 months, as summarized in **Table 11** below.

Table 11. Responder Rate in UII Summary at Month 6 – mITT Analysis Set (n=130) - Imputed

	Estimate (%)	Lower 95% CI	Upper 95% CI	P-value (2-sided)
Patients with $\geq 50\%$ reduction from baseline in UIIs per day	82.9%	76.4%	89.4%	<0.0001

Note: The imputation model includes baseline age, investigational site, baseline UII episodes, and all available follow-up visit UII episodes through 6 months. It uses full conditional specification and 100 imputed data sets.

The primary endpoint was also analyzed for additional study groups at 6 months, as summarized in **Table 12** below.

Table 12. Primary Endpoint for Various Analysis Sets at Month 6 - Imputed

Patients with $\geq 50\%$ reduction from baseline in UIIs 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%

* $p < 0.0001$; ¹The worst case assumes all missing responses are failures. The estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

Note: The imputation model includes baseline age, investigational site, baseline UII/ episodes, and all available follow-up visit UII episodes through 6 months. It uses full conditional specification and 100 imputed data sets.

Table 13 presents data imputed for primary endpoint sub-group analysis at 6 months, based on the responder rate for UII episodes, for sex, age, race, baseline UII episodes and geographic region.

Table 13: Primary Endpoint Subgroup Analysis at Month 6 – mITT Analysis Set (N = 130) - Imputed

Patients with $\geq 50\%$ reduction from baseline in UIIs per day	Estimate (%)	Lower 95% CI	Upper 95% CI³
Female (N=128)	82.6%	76.0%	89.2%
Male ¹ (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 UIIs <8 (N=117)	84.4%	77.8%	91.0%
Baseline UIIs ≥ 8 ² (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%

¹The subgroup does not contain any missing response values following the imputation of failures. Therefore, the estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

²The subgroup contains a single missing response value. The imputation model results in zero between-imputation variance. Therefore, the single missing value is imputed with the result of the multiple imputation value for that patient, and estimate is based on the data summary without multiple imputation modelling. Z-test statistic is displayed instead of t.

³If the imputation results in an upper 95% CI >100%, the value will be forced at 100%.

Note: The imputation model includes baseline age, investigational site, baseline UII episodes, and all available follow-up visit UII episodes through 6 months. It uses full conditional specification and 100 imputed data sets.

Table 14 shows the secondary effectiveness endpoints related to urinary symptoms at 6 months.

Table 14. Secondary Effectiveness Results at Month 6 – mITT Analysis Set (N=130) - Imputed

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

¹ The imputation model includes baseline age, investigational site, baseline data, and all available follow-up measures through 6 months. It uses full conditional specification and 100 imputed data sets.

For the secondary effectiveness endpoints in **Table 14**, the first three endpoints (i.e., reduction from baseline in the mean number of UUI episodes per day, improvement from baseline in ICIQ-OABqol score, and the percentage of patients who experienced an improvement in ICIQ-OABqol of at least 10 points) supported the findings from the primary endpoint in improvement in 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.

5.2.5.2 Twelve-Months Results (Secondary Endpoint)

For patients with an attempted implant (N=130), 77.7% of patients at Month 12 were responders (≥ 50% reduction from baseline in UUIs per day), as summarized in **Table 15** below.

Table 15. Responder Rate in UUI Summary at Month 12 – mITT Analysis Set (n=130) - Imputed

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

Note: The imputation model includes baseline age, investigational site, baseline UUI episodes, and all available follow-up visit UUI episodes through 12 months. It uses full conditional specification and 100 imputed data sets.

This endpoint was also analyzed for additional study groups, as summarized in **Table 16** below.

Table 16. Responder Rate for Various Analysis Sets at Month 12 - Imputed

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. The estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

Note: The imputation model includes baseline age, investigational site, baseline UUI episodes, and all available follow-up visit UUI episodes through 12 months. It uses full conditional specification and 100 imputed data sets.

Table 17 presents data imputed for primary endpoint sub-group analysis at 12 months, based on the responder rate for UUI episodes, for sex, age, race, baseline UUI episodes and geographic region.

Table 17: Responder Rate Endpoint Subgroup Analysis at Month 12 – mITT Analysis Set (N = 130) - Imputed

Patients with ≥ 50% reduction from baseline in UUIs per day	Estimate (%)	Lower 95% CI	Upper 95% CI ³
Female (N=128)	77.4%	70.0%	84.8%
Male ¹ (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 ¹ (N=7)	57.1%	20.5%	93.8%
Baseline UUIs <8 (N=117)	79.5%	72.0%	87.0%
Baseline UUIs ≥8 ² (N=13)	61.5%	35.1%	88.0%
US (N=124)	77.5%	70.0%	85.0%
EU ¹ (N=6)	83.3%	53.5%	100.0%

¹ The subgroup does not contain any missing response values following the imputation of failures. Therefore, the estimates are based on data summaries without multiple imputation modelling. Z-test statistic is displayed instead of t.

² The subgroup contains a single missing response value. The imputation model results in zero between-imputation variance. Therefore, the single missing value is imputed with the result of the multiple imputation value for that subject, and estimate is based on the data summary without multiple imputation modelling. Z-test statistic is displayed instead of t.

³ If the imputation results in an upper 95% CI >100%, the value will be forced at 100%.

Note: The imputation model includes baseline age, investigational site, baseline UUI episodes, and all available follow-up visit UUI episodes through 12 months. It uses full conditional specification and 100 imputed data sets.

Table 18 shows the secondary effectiveness endpoints related to urinary symptoms at 12 months post-implant.

Table 18. Secondary Effectiveness Results at Month 12 – mITT Analysis Set (N=130) - Imputed

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

The imputation model includes baseline age, investigational site, baseline data, and all available follow-up measures through 12 months. It uses full conditional specification and 100 imputed data sets.

5.3 Conclusions

5.3.1 Effectiveness Conclusions

The results from the SANS-UUI study show that SNM therapy provides a clinically meaningful improvement in symptoms of urge urinary incontinence in patients who have failed, could not tolerate, or were not a candidate for more conservative treatments. For the mITT analysis set, 82.9% and 77.7% of patients had a $\geq 50\%$ reduction from baseline in UUIs per day at 6 months and 12 months post-implant, respectively.

The secondary effectiveness endpoints in the clinical study as measured by improvements in urinary symptoms including reduction in UUI episodes and ICIQ-OABqol scores also supported improvement in symptoms of UUI by the Neuspera SNM System.

5.3.2 Safety Conclusions

In the SANS-UUI study of the Neuspera SNM System, there were no serious device-related AEs and one serious procedure-related AE reported. At the twelve-month endpoint, there were a total of 27 device-related events in 21 of 130 (16.2%) patients and 21 procedure-related events in 19 of 130 patients (14.6%).

At the twelve-month endpoint, the most common device-related AEs in the SANS-UUI study were implant migrations (3.1% of patients), device stimulation issue (2.3%), implant fractures (1.5%), implant site pain (1.5%), medical device pain (painful stimulation due to high amplitude stimulation or after a fall) (1.5%), and medical device site burn (WT placed directly on skin) (1.5%). No other device-related AE occurred more than once ($<0.8\%$ of patients). There were no infections at the site of the implant.

At 12 months, there were 2 device fractures, 5 device migrations in 4 patients, 5 revisions, and 21 device explants. The majority of the migrations occurred within the first month of implant, and the fractures occurred on Day 26 and Day 63. However, one additional device fracture was seen after the 12-month data lock and was attributed to chiropractic manipulation.

6 USE ENVIRONMENTS

Neuspera procedures will occur in hospitals, surgery centers, and clinics.

7 PROCEDURE OVERVIEW

Refer to the sections on Intended Use and Adverse Events.

Note: *Inspect the outer pouch for signs that it has been damaged or the sterile seal has been broken. If there are signs of damage or the sterile seal is broken, retain for collection by Neuspera and replace with a new kit.*

7.1 Patient Selection

Patients should be appropriate candidates for therapy evaluation and for potential surgical implant of an SNM system. Patients are contraindicated for therapy evaluation if their sacral depth measured from skin to the S3 foramen is greater than 10 cm as confirmed by imaging and they are unable to properly operate the Trial System.

The Trial System is intended to be used continuously during the stimulation trial. If the patient experiences a 50% reduction in urinary urge incontinence symptoms after the trial stimulation, they may 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.

The safety and effectiveness of using the Neuspera System has not been established in the following:

- Patients with BMI > 40,
- Pregnant women,
- Pediatric patients,
- Bilateral stimulation with the permanent Neuspera SNM System (bilateral stimulation may be used with Trial System),
- Patients with neurologic cause of OAB such as multiple sclerosis, diabetes, or Parkinson's disease.

7.2 Sacral Assessment

IMPORTANT:

- **Ensure that x-ray imaging according to the Neuspera Radiographic Imaging Guidance is conducted and that sacral depth assessment is conducted and approved by Neuspera prior to the trial or implantation procedure.**
 - **NOTE: If the sacral depth is too great, the Neuspera SNM Permanent System should not be used as the implant may not be able to be powered and may require an explant. For these patients, a different SNM device should be selected.**
- **A Neuspera Field Clinical Engineer (FCE) is required to be present at each trial and implantation procedure. Please contact your local sales representative or call (888) 846-8332 or email Physicianhelp@neuspera.com to ensure an FCE will be present at the procedure.**

7.3 Procedure

7.3.1 Lead Implant Procedure Preparation

- Place the patient in a prone position with hips supported by a pillow or bolster for patient comfort.
- Prep the patient's lower back and sacral area laterally to the hips. Extend to presacral area and top of buttocks for sterile surgery.
- Arrange sterile drapes to allow visualization of the intergluteal fold and pre sacral area.
- Attach the ground pad to the External Stimulator.
- Communicate with patient that ground pad will be placed on the arch area of the foot. Apply the ground electrode with connected External Stimulator to the arch of the patient's foot. Ground pad placement should avoid heavily calloused areas of the sole of the foot (e.g., the ball and heel). If the entire sole of a patient's foot is dry and calloused, ground pad should be adhered to the posterior skin of the patient's calf or the top of the foot.

- (if performing without fluoroscopy) Use surgical marker and ruler to locate the left and right S3 foramen (approximately 9 cm from the tip of the coccyx and 2 cm from the midline).
- (if performing with fluoroscopy) Move the C-Arm into the AP position to provide fluoroscopic mapping of the S3 sacral region to allow for location of midline of sacrum, sacroiliac joints, sciatic notches, medial foraminal borders and the sacral foramina.
- Administer local anesthesia in the area of skin over the targeted sacral foramen. Inject anesthesia in the skin to obtain a *peau d'orange* effect. Next touch the sacral periosteum and flood the plane with local nearby. Be careful not to inject anesthesia into the foramen to prevent anesthetizing the sacral nerve.

7.3.2 Needle Placement and Test Stimulation

- (if performing without fluoroscopy) Insert foramen needle into the sacral foramen. Keep an approximate 60-degree insertion angle relative to the skin. Inserting the needle 2 cm above the marked S3 location will help maintain this 60-degree angle.
- (if performing with fluoroscopy) Insert foramen needle approximately 2 cm cephalad to the sacroiliac joints and 2 cm lateral to sacral midline, feeling for foraminal margins until the S3 foramen is identified and penetrated. If necessary, adjust positioning by removing the needle and reinserting. Using fluoroscopy, ensure the foramen needle is inserted into the foramen with an approximate 60-degree insertion angle relative to the skin. The needle should enter the foraminal canal perpendicular to the bony surface (This will position the needle parallel to the nerve). Confirm the location, orientation, and depth of the needle fluoroscopically and, if necessary, adjust positioning by removing the needle and reinserting.
- Stop the needle with the tip no deeper than around 1.5cm below the periosteum/posterior aspect of foramen. This is usually where the desired stimulation response usually occurs. The depth below the posterior aspect is determined by looking visually at the needle markings.
- Pass the pin end of the Intraoperative cable outside of the sterile field. Once outside, remove the pin cover and connect the pin end of the Intraoperative Cable to the white connector of the External Stimulator.
- Attach the intraoperative cable to the non-insulated proximal section of the foramen needle.
- Choose an appropriate Program to test stimulation (i.e. Electrode 0 to anode (Ground Pad), electrode 1 to cathode (intraoperative cable)). Place the Wireless Transmitter over the External Stimulator. Increase stimulation output using the Clinician Programmer. Observe the patient's S3 motor and/or sensory response.
- Ask the patient to describe the sensation of the stimulation. Also include the location (pelvic floor, vagina, testes, rectum/anus, bladder, scrotum, etc.) and quality (pulling, tapping, etc.) of the sensation.
- If the desired responses are not seen, reposition the needle higher and/or more medially in the foramen and/or change the angle of the needle as deemed appropriate. If the response is still not as desired, test at one foramen level below or the contralateral side.
- Repeat steps above for contralateral foramina or other foramina chosen.
- When testing is complete, take the Wireless Transmitter away from the External Stimulator. Turn Wireless Transmitter power OFF on the Clinician Programmer. Place magnet on Wireless Transmitter.

7.3.3 Trial Lead Placement

- Remove the stylet from the foramen needle.
- Insert the Trial Lead into the foramen needle. Align the appropriate depth marker on the Trial Lead with hub of the foramen needle. The electrode at the distal end of the Trial Lead will extend from the needle tip when the more distal lead marker is aligned with the needle hub.
- Attach the intraoperative cable to the proximal connector of the Trial Lead.
- Choose an appropriate Program to test stimulation (i.e. Electrode 0 to anode (Ground Pad), electrode 1 to cathode (intraoperative cable)). Place the Wireless Transmitter over the External Stimulator. Test the Trial Lead placement by stimulating and observing patient motor and/or sensory responses. If necessary, reposition the lead within the foramen if optimal responses are not obtained.
- Using the Clinician Programmer, slowly increase the stimulation amplitude until a response is observed or sensory response is felt by the patient. Ideally, the sensory or motor threshold should be 2 Volts or less.
- When the Trial Lead is in the desired location, disconnect the intraoperative cable from the lead. Carefully withdraw the foramen needle over the Trial Lead. Then free the stylet hub from the stylet handle, and then remove the Trial Lead stylet leaving the Trial Lead in place.
- Reconnect the intraoperative cable to the proximal end of the Trial Lead. Test stimulation to confirm the lead placement.
- Repeat the Trial Lead placement for the contralateral side, if desired.

7.3.4 Connecting the External Stimulator

- Clean the area where External Stimulator/Ground Pad will be attached.
- Dress the Trial Lead implant site with gauze. Coil the excess Trial Lead to provide strain relief and minimize the unsecured cable length. Use adhesive dressing to cover the coiled lead while leaving approximately 3 cm of the distal end of the lead free on the side of the adhesive dressing (enough for insertion into lead connector on the External Stimulator).
- Connect the External Stimulator to the Ground Pad. Apply the Ground Pad and External Stimulator to the skin of lower back near the coiled lead or side of the patient (cannot be on adhesive dressing). Connect the Trial Lead end to the lead connector of the Neuspera External Stimulator (white connector goes to the left Trial Lead, black connector goes to the right Trial Lead). Place gauze under the connectors to protect the patient's skin.
- Apply adhesive dressing to cover the uncovered portion of Trial Lead and the lead connector of the External Stimulator.

7.4 Post-Operative Patient Training and Follow-up Instructions

After the patient has recovered from the procedure, the stimulation therapies programmed to the Wireless Transmitter (see Therapy Configuration section of this manual) should be checked to ensure that the stimulation amplitude is high enough for the patient to feel, but low enough to be comfortable. Be sure to check all programs. Ask the patient to describe the sensations (location and intensity) that they feel at different stimulation amplitudes and with the different pre-set programs. Unlike use with the permanent system, for the trial period the stimulation will be continuous from the External Stimulator and will not require the Wireless Transmitter for stimulation. The Wireless Transmitter is needed only to adjust the stimulation and should then be removed. The External Stimulator will

continue to stimulate as programmed as long as the Orange U-Clip remains in the closed (flush) position.

7.4.1 Patient Training

- Ensure the patient is provided with the following items:
 - Wireless Transmitter (WT)
 - Patient Controller and accessory cables
 - Charging Pad and accessory cables
 - Magnet
- Train the patient on how to place the Wireless Transmitter over the External Stimulator and use their Patient Controller to adjust amplitude and turn therapy off/on.

7.4.2 Test Stimulation

- Have the patient place the Wireless Transmitter over the External Stimulator.
- Ensure Programs 1 & 2 on clinical programmer correspond to left and right sided lead (corresponding (+) anode and (-) cathode configurations)
 - If two Trial Leads were placed:
 - For left lead program, set left lead (E1) to cathode (-), right lead (E2) to anode(+)
 - For right lead program, set left lead (E1) to anode (+), right lead (E2) to cathode (-)
 - Or E1 left (-), E0 ground pad (+)
 - Or E2 right (-), E0 ground pad (+)
 - If a single lead placed, set lead to cathode (-), ground pad to anode (+)
- Ensure amplitude is set to 0.2V (minimum)
 - Select Program 1, turn on Wireless Transmitter power, starting at 0.2 V and increase the stimulation amplitude until patient feels stimulation and is comfortable. Record the location of sensation.
 - Turn stimulation off, and go to Program 2.
 - Repeat steps for the other Trial Lead.
- Select the main program based on stimulation test and sensory response.
 - Select program and leave the stimulation ON.
 - Verify patient feels stimulation.
- Remove the Wireless Transmitter. Place the magnet on the Wireless Transmitter to turn the Wireless Transmitter off and conserve battery.
- Once magnet is on Wireless Transmitter, turn off the Patient Controller. Since the magnet is on Wireless Transmitter and the Patient Controller is disconnected from Wireless Transmitter, no programming can be done. The External Stimulator will continue to stimulate as programmed as long as the Orange U-Clip remains in the closed (flush) position.
- Patient should be Instructed on how to do the following:
 - Change stimulation amplitude
 - Change left/right lead
 - Use, reset, and charge the wireless transmitter
 - Use and charge the patient controller
 - Apply extra dressing, if needed
 - Replace Ground Pad, if needed
 - Complete the Bladder Diary

- Call Provider, if any issues present
- Use the U-Clip emergency off switch, if needed
- Limiting activities (see Patient Activities section below)

7.4.3 Home-use (up to 7 days)

The patient may perform the following operations.

- Increase or decrease stimulation amplitude:
 - Remove magnet from Wireless Transmitter
 - Place Wireless Transmitter over the External Stimulator
 - Turn on Patient Controller
 - Ensure Wireless Transmitter power ON
 - Adjust stimulation amplitude
 - Remove Wireless Transmitter and place magnet on Wireless Transmitter. Programming is set.
 - Turn off Patient Controller.
- Changing programs:
 - Remove magnet from Wireless Transmitter
 - Place Wireless Transmitter over the External Stimulator
 - Turn on Patient Controller
 - Turn the Wireless Transmitter power ON on the Patient Controller
 - Ensure the Wireless Transmitter power is OFF on Patient Controller (stimulation should stop at this point)
 - Change the program
 - Turn the Wireless Transmitter power ON on the Patient Controller
 - Adjust stimulation amplitude as necessary
 - Remove the Wireless Transmitter and place magnet on the Wireless Transmitter
 - Turn off Patient Controller
- Stop stimulation:
 - Remove magnet from Wireless Transmitter
 - Place Wireless Transmitter over the External Stimulator
 - Turn on Patient Controller
 - Turn the Wireless Transmitter power ON on the Patient Controller
 - Turn the Wireless Transmitter power OFF on Patient Controller (stimulation should stop at this point)
- Reset the Wireless Transmitter:
 - 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 the reset (ensure the teardrop point of the magnet is aligned with the teardrop point of the Wireless Transmitter (**Figure 4**))
 - After 5-10 seconds, remove magnet from the Wireless Transmitter. Do not leave magnet on Wireless Transmitter while it is charging.

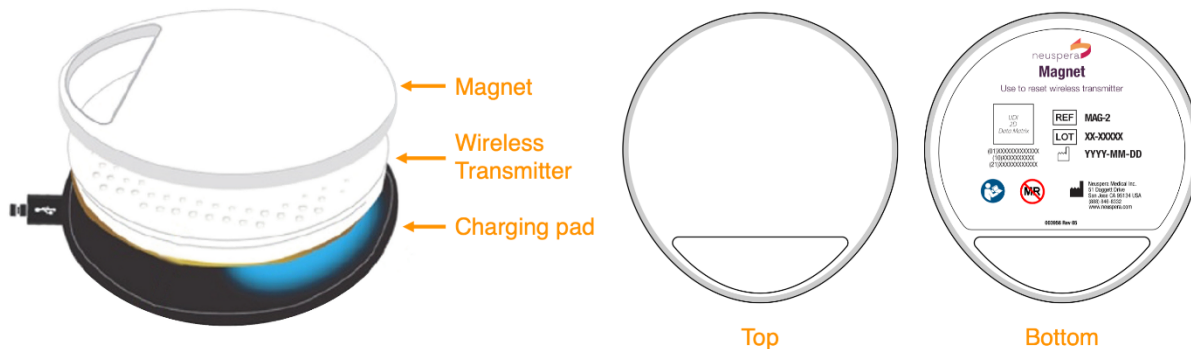


Figure 4. Resetting the Wireless Transmitter. Place the label side of the magnet (bottom of magnet) on the Wireless Transmitter for 5-10 seconds. The top of the magnet is visible during correct placement. Remove magnet after reset is completed. Do not leave magnet on Wireless Transmitter while it is charging.

NOTE: To stop stimulation quickly, the patient can pull the Orange U-Clip from the External Stimulator.

Most household appliances and equipment that are working properly and grounded properly will not interfere with the Neuspera Trial System. The following equipment is generally safe if patients 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: Keep the Wireless Transmitter away from the burners while the burners are turned on.
- Power tools: Keep the motors away from the Wireless Transmitter.
- Avoid close proximity to high power wireless power transfer equipment such as laying between Electric Vehicle (EV) wireless chargers and the vehicle

Notify the patient that the Trialing System should be removed from the patient prior to receiving any 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

7.5 Trial System Removal (in-office)

The Neuspera SNM Trial System is used for a test period to evaluate if a patients should be treated with the Neuspera Permanent SNM System. Trial stimulation should not exceed 7 days. Patients should experience a 50% reduction in urinary urge incontinence symptoms prior to proceeding to a permanent implant.

To remove the Trial System, follow these steps:

- Turn off the External Stimulator using the Wireless Transmitter and Clinician Programmer or Patient Controller
- Remove External Stimulator and Ground Pad from skin
- Disconnect Trial Lead(s) from the External Stimulator
- Remove the dressing
- Use gentle traction to remove the Trial Lead(s) (Note: the Trial Lead is expected to expand during removal)
- Cover wound with a bandage
- Dispose of External Stimulator, Trial Lead(s), and Ground Pad according to local environmental regulations

8 CLINICIAN PROGRAMMER OVERVIEW

The Clinician Programmer enables management of the Wireless Transmitters associated with a patient's external stimulator, programming of a patient's stimulation therapy into their Wireless Transmitter, review of a patient's therapy statistics, and connection of a Patient Controller to a Wireless Transmitter.

There are four (4) primary views in the Clinician Programmer (**Figure 5**):

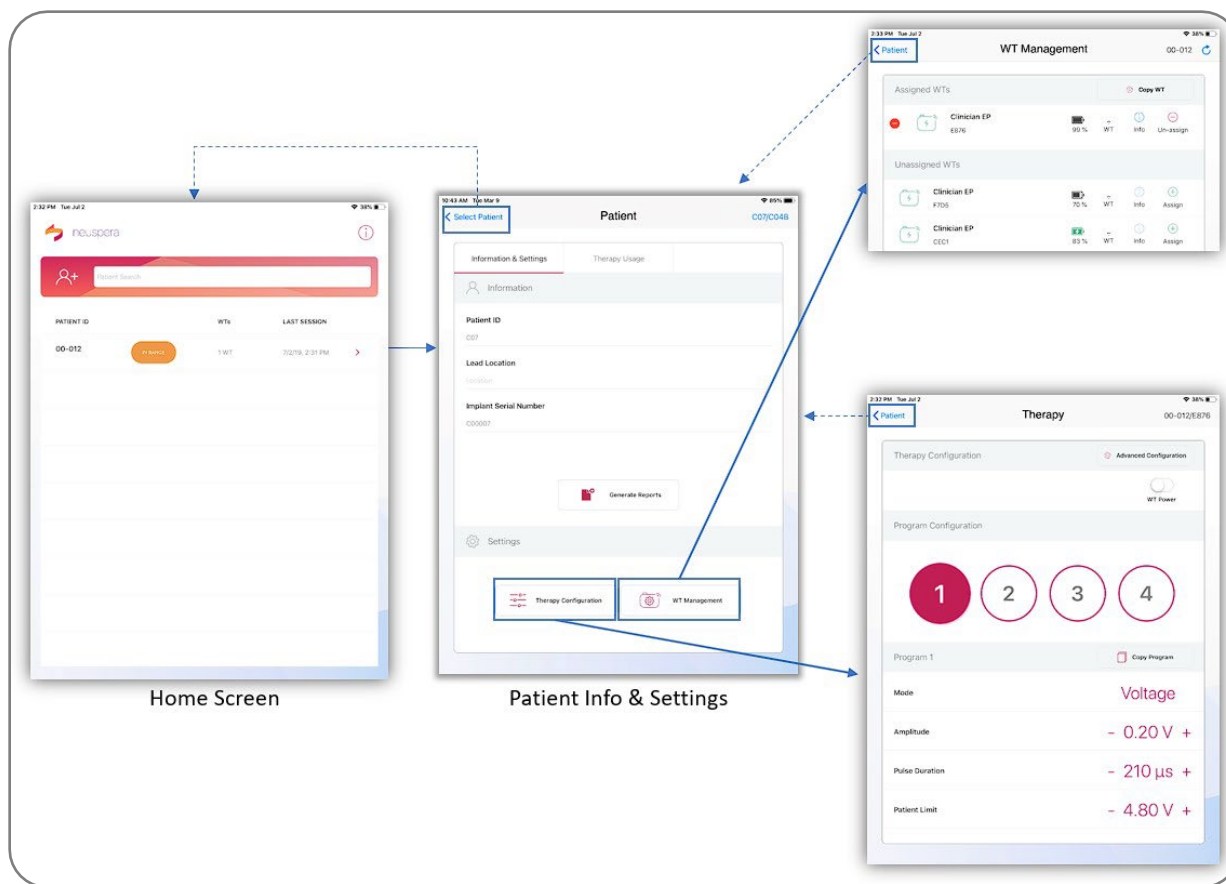


Figure 5. Navigating through the 4 most commonly used screens on the Clinician Programmer

9 SETTING UP A PATIENT PROFILE

To set up a new patient profile, tap the “add person” icon on the Home screen (**Figure 6**). This will open the patient profile page where you can enter the patient ID and External Stimulator serial number (found on the Neuspera Trial kit label).

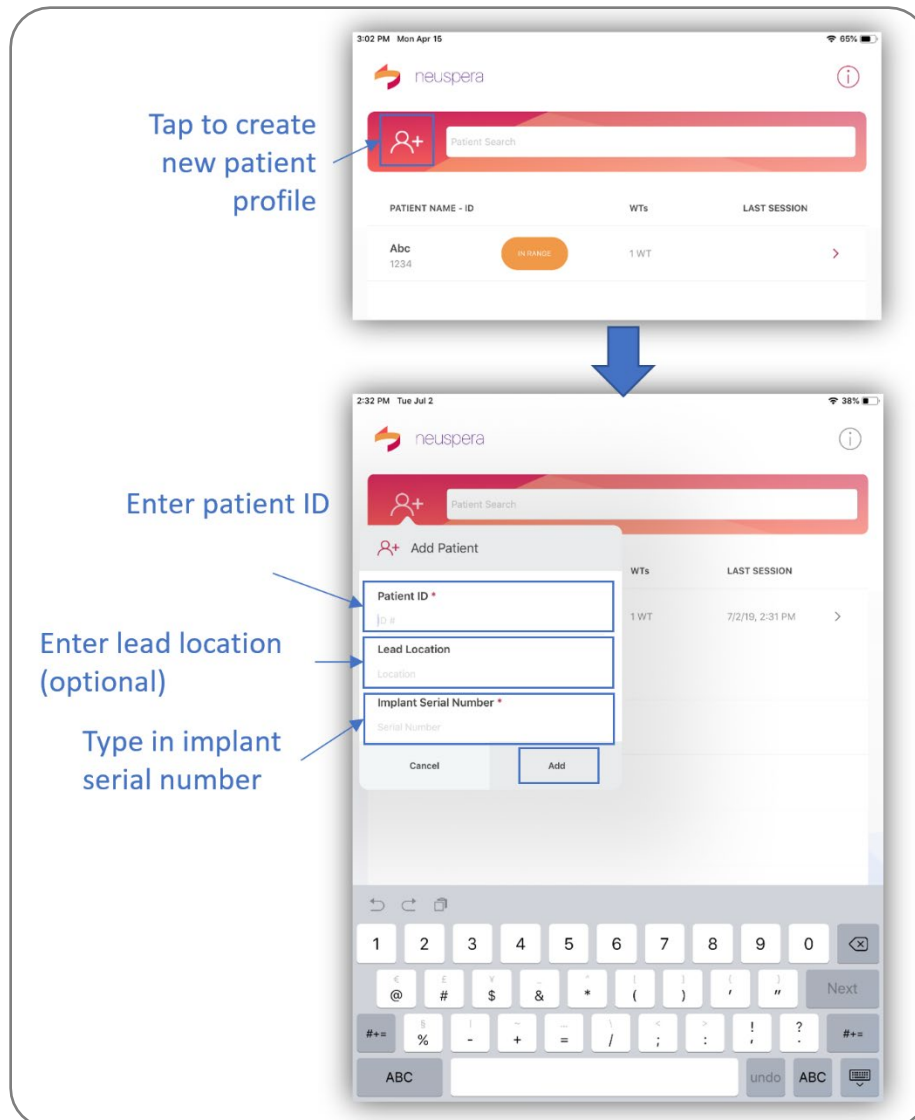


Figure 6. Setting up a new patient profile

Note: A Wireless Transmitter will not be able to link to the patient's External Stimulator unless the correct serial number is entered.

10 WIRELESS TRANSMITTER MANAGEMENT

To assign or unassign a Wireless Transmitter to a patient, tap on "WT Management" from the Patient Information & Settings screen (**Figure 7**).

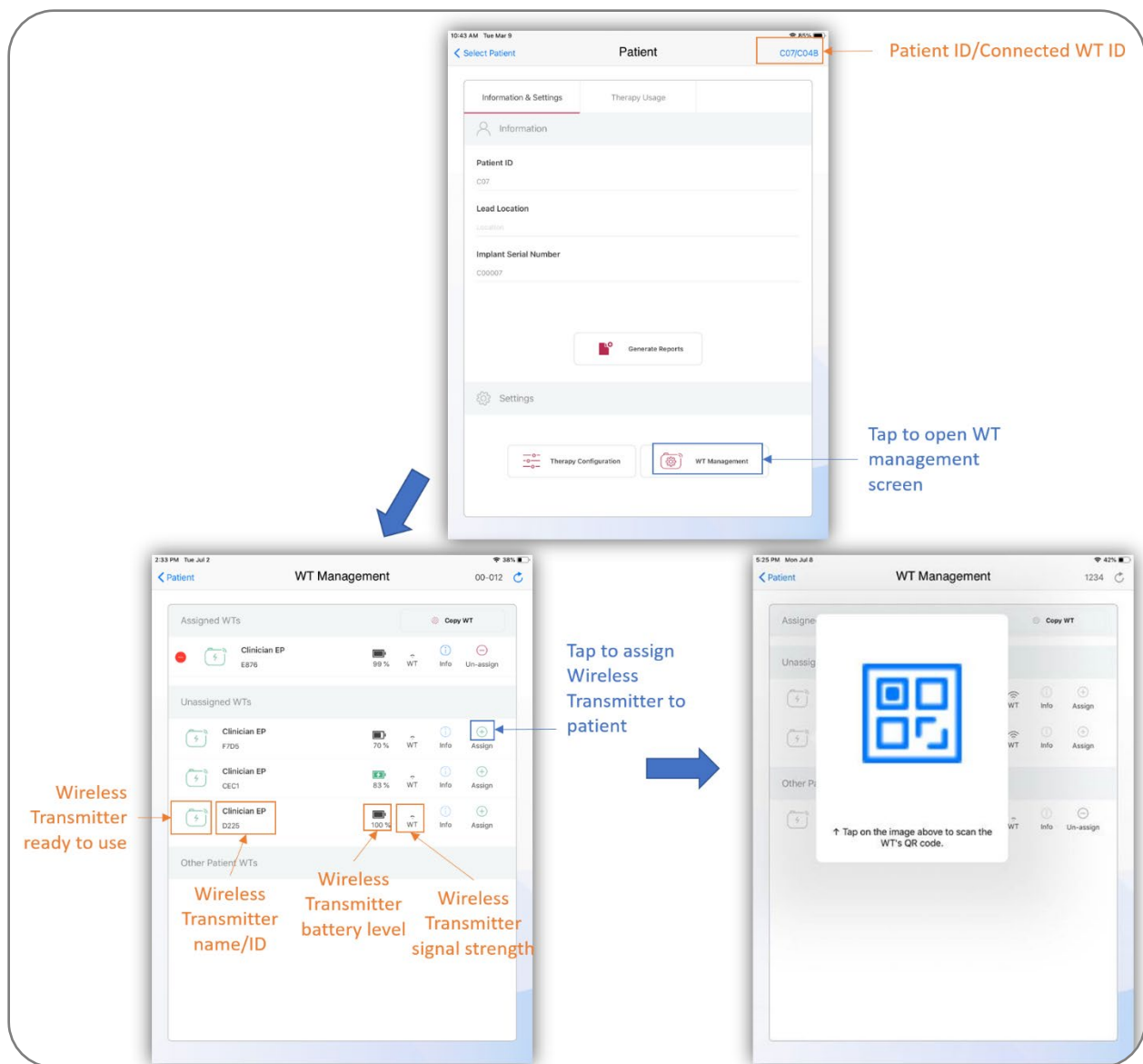


Figure 7. Assigning Wireless Transmitters to a patient's profile.

All Wireless Transmitters that are within range and transmitting a Bluetooth® signal will appear on the WT Management screen. Select an unassigned Wireless Transmitter and assign it to the patient by tapping the green "+" Assign icon.

After clicking "+", the App must scan the QR code on the Wireless Transmitter to complete the authenticated assignment. Tap on the blue QR code icon to activate the device's camera and hold it over the QR code on the Wireless Transmitter (or Wireless Transmitter's box label) until the code is recognized (see **Figure 8** for locations of QR code on Wireless Transmitter and box label).

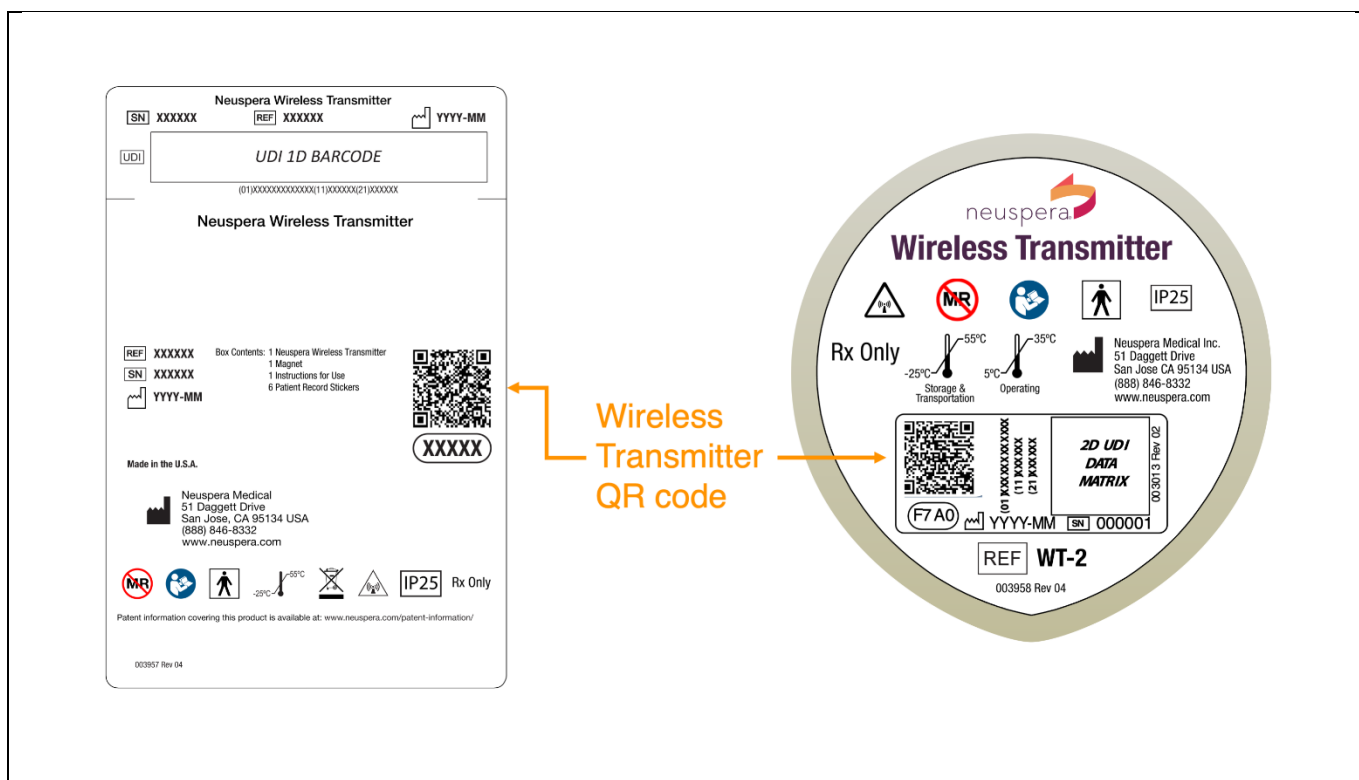


Figure 8. Location of Wireless Transmitter QR code on the Wireless Transmitter (left) and the Wireless Transmitter box label (right).

If an incorrect Wireless Transmitter is assigned to a patient, tap on the red “-” Unassign icon (**Figure 9**).

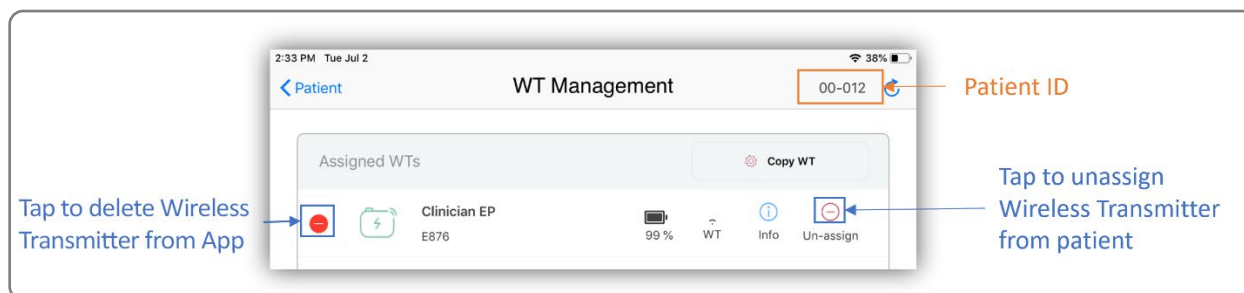


Figure 9. Unassigning a Wireless Transmitter from a patient's profile

Note: Do not use the Delete button to unassign a Wireless Transmitter from a patient. This will only delete the entry from this Clinician Programmer App view; it will not unassign the Wireless Transmitter from the patient, and the Wireless Transmitter will still appear on the Patient Controller.

After pairing with the External Stimulator, confirm pairing 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.

11 THERAPY CONFIGURATION

To set up or modify a patient's stimulation therapy, tap "Therapy Configuration" at the bottom of the Patient Information & Settings screen to open the Therapy screen (**Figure 10**).

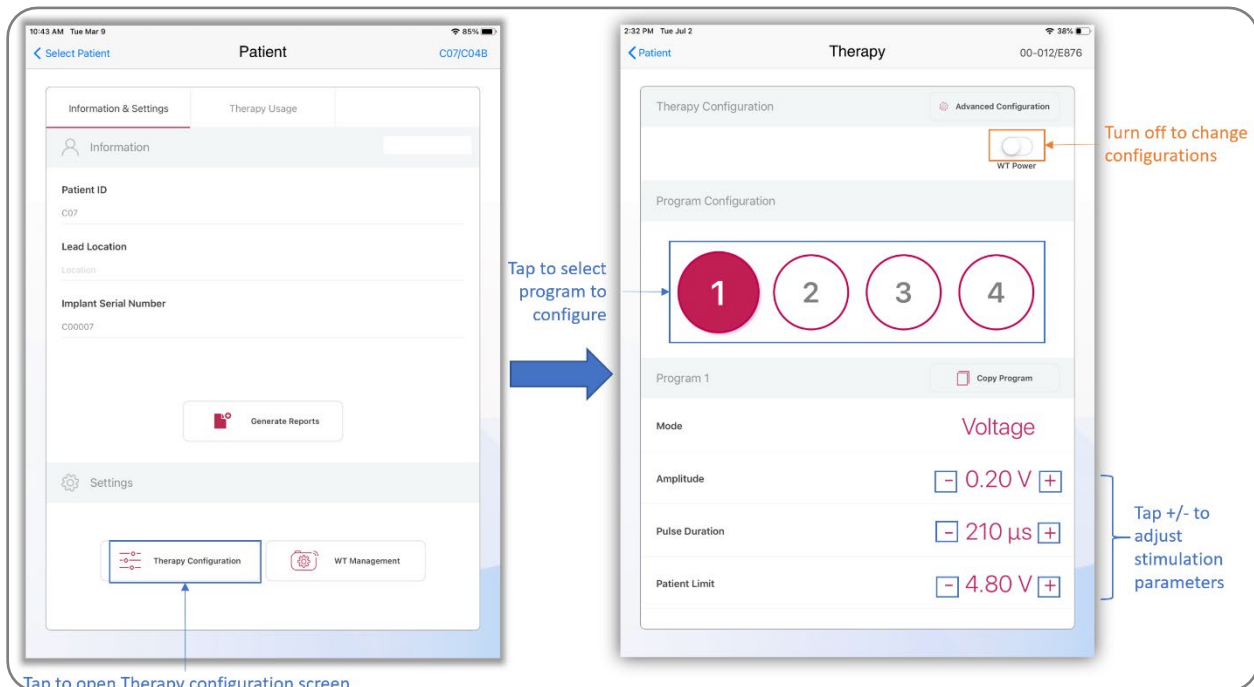


Figure 10. Therapy Configuration

11.1 Program Configuration

1. Tap on the circle "1" to start configuring program 1.
2. Tap on the Amplitude "-" to decrease or "+" to increase the stimulation amplitude (range 0.2-4.8 V in 0.1 V increments below 1.0 V and 0.2 V increments above 1.0 V).
3. Tap on the Pulse Duration "-" to decrease or "+" to increase the stimulation pulse duration (range 105-945 μ s in 15 μ s increments).
4. Set RF power to 25% or less.
5. Tap on the Patient Limit "-" to decrease or "+" to increase the maximum stimulation amplitude to which the patient can increase stimulation.

Note: Amplitude is the only stimulation parameter the patient can change on their own for a given program.

6. Repeat the above steps for any additional programs desired.

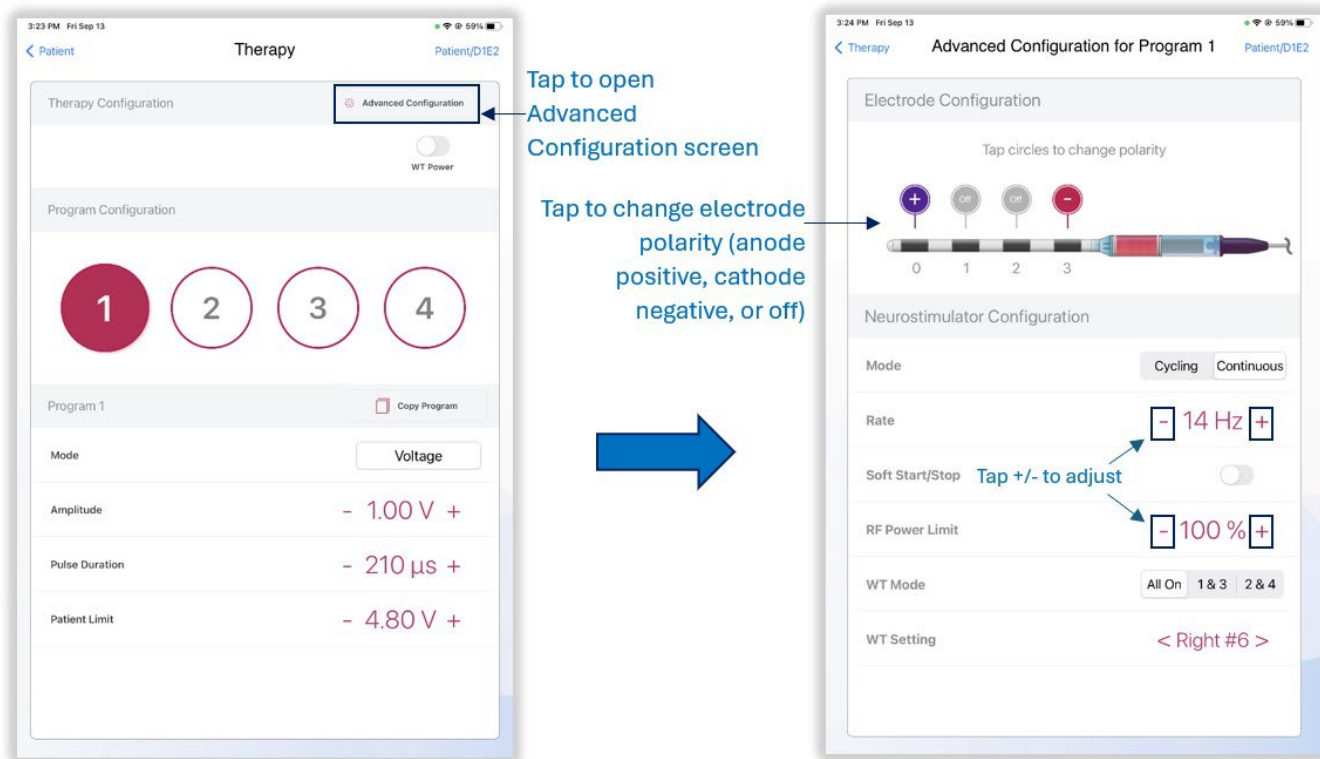


Figure 11. Advanced configuration screen to configure electrode settings

To program the External Stimulator, use the Electrode Settings listed in the Table below.

Electrode connection in CP	Function on External Stimulator
0	Ground Pad (button connector)
1	White connector
2	Black connector
3	Pairing Test indicator (activate by setting only this electrode to + with >3V)

11.2 Patient Controller Connection

To allow a Patient Controller to view or adjust the therapy settings in the Wireless Transmitter, an authenticated link between the Patient Controller and the Wireless Transmitter must be established using the Clinician Programmer.

Click the “Info” icon on the WT Management screen to open a screen with a QR code unique to the patient’s Neurostimulator and assigned Wireless Transmitter (see Figure 12).

Note: The QR code generated by the Clinician App is NOT the same QR code that is on the Wireless Transmitter label.

See **Figure 13**, for how to prepare the Patient Controller for a new Wireless Transmitter connection.

- If the Patient Controller is not already connected to a Wireless Transmitter, the Patient Controller App will prompt to scan the QR code when the Patient Controller App is opened (**Figure 13**, left image).

- If additional Wireless Transmitters are being connected, tap on the prompt next to “Connect to a New WT” from the Patient Controller App Info screen (**Figure 13**, right image). This will open the QR prompt screen. Tap on the blue QR code icon to activate the camera on the Patient Controller and hold over the QR code displayed by the Clinician Programmer App.

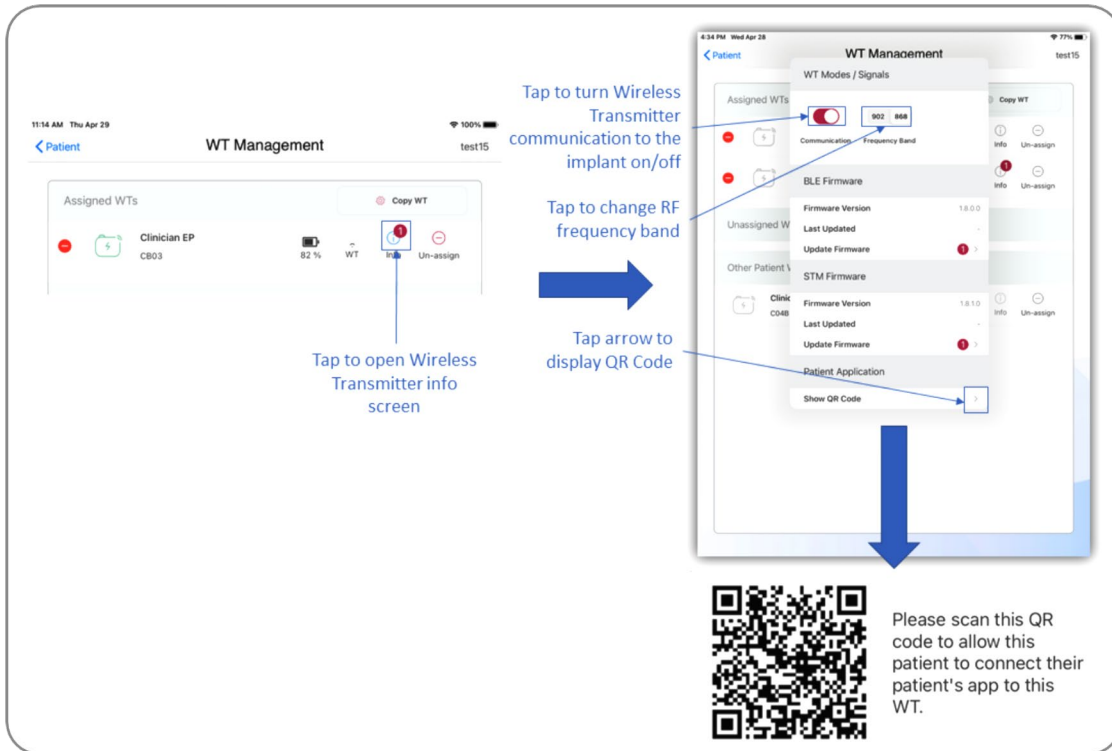


Figure 12. Wireless Transmitter info screen and QR code to connect a Wireless Transmitter to a Patient Controller.

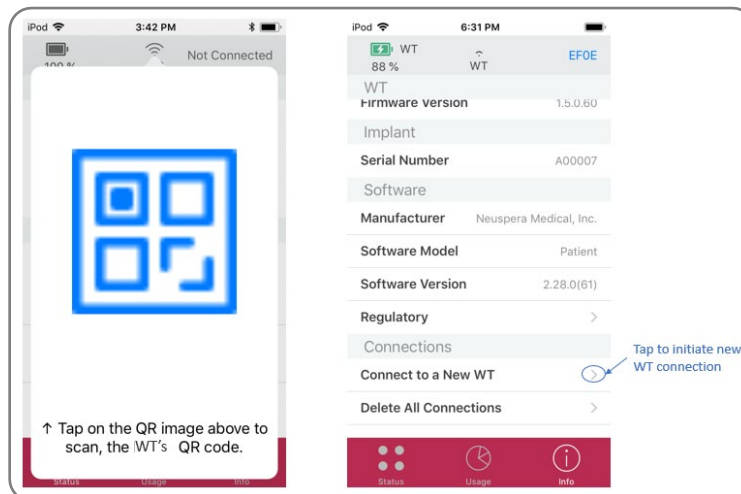


Figure 13. Patient Controller App screens for connecting to a Wireless Transmitter

Left image: QR code prompt to a New WT. Right image: App Info screen for a Patient Controller App already connected to at least one Wireless Transmitter. Adjusting Patient Stimulation Therapy Settings

If necessary to optimize the patient's therapy, stimulation settings and preset programs can be adjusted when the patient's Wireless Transmitter is within range of the Clinician Programmer. Refer to "Therapy Configuration" section of this manual.

Note: Each Wireless Transmitter must be separately connected to the Clinician Programmer and updated.

Note: To ensure that the Wireless Transmitter is properly updated with any adjustments made by the Clinician Programmer App, turn the Patient Controller App communication off from the Patient Controller App Info Screen (see **Figure 14**).

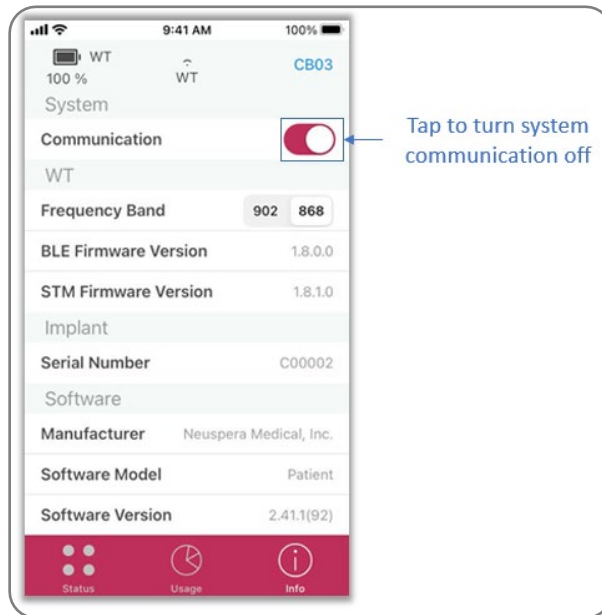


Figure 14. Patient Controller App Info screen.

11.3 Updating Apps or Wireless Transmitter Firmware

Occasionally, new versions of the Clinician Programmer or Patient Controller Apps or the Wireless Transmitter firmware will be released. Devices should be updated in a timely manner.

12 TROUBLESHOOTING

Common problems encountered with the Clinician Programmer App are listed below. If these do not solve the problem, contact Neuspera Medical. For additional problems that patients may experience with the Patient Controller App, please refer to the Patient Manual for the Neuspera SNM System.

Problem	Potential Cause	Recommended Resolution
Clinician Programmer cannot find Wireless Transmitter.	Wireless Transmitter battery is not charged.	Charge Wireless Transmitter.
	Clinician Programmer and Wireless Transmitter are too far away from each other.	Move Wireless Transmitter to within 1 meter (3 feet) of Clinician Programmer.
Clinician Programmer cannot connect to displayed Wireless Transmitter.	Wireless Transmitter battery is too low.	Charge Wireless Transmitter and retry connection.
Patient's Wireless Transmitter is listed under "Other Patient WTs".	Wireless Transmitter is associated to a different Neurostimulator or External Stimulator serial number.	Confirm the correct External Stimulator serial number is listed in the Patient's profile. If it is certain that the Patient's profile has the correct serial number, unassign the Wireless Transmitter by clicking on the red "-" unassign icon (see Figure 9) and then assign the Wireless Transmitter to the patient (see Figure 7). Note: When a Wireless Transmitter is reassigned, it must also be reassigned to the Patient Controller. On the Patient Controller's Info screen, "Delete all Connections" and then relink the Wireless Transmitter to the Patient Controller (see Figure 7 Error! Bookmark not defined.).
Wireless Transmitter does not power on External Stimulator.	Wireless Transmitter is too far from External Stimulator (Wireless Transmitter must be directly over External Stimulator).	Place Wireless Transmitter directly over External Stimulator
	Wireless Transmitter battery is too low (Wireless Transmitter will not connect to External Stimulator if <10% battery).	Charge Wireless Transmitter to at least 10%.
	Wireless Transmitter is not assigned to External Stimulator.	Confirm that the correct External Stimulator serial number is in the patient profile (see Figure 6).
Clinician Programmer display doesn't turn on.	Clinician Programmer is turned off.	Turn Clinician Programmer on by pressing button on top edge of Clinician Programmer.

Problem	Potential Cause	Recommended Resolution
	Clinician Programmer battery is too low.	Charge device for at least 2 minutes and while still plugged in, turn Clinician Programmer on by pressing button on top edge of Clinician Programmer.
System is not responsive or not behaving as expected.	Possible EMI.	Move away from the interfering source (see EMI notes at the end of this manual).

13 CLINICIAN PROGRAMMER APP MESSAGES AND RESOLUTIONS

System Message	Cause	Resolution
Action Not Available Cannot change settings while Therapy is active OK	User tries to change stimulation settings while External Stimulator is delivering stimulation (only changes in amplitude are allowed while therapy is enabled).	Tap "OK" to close message. Turn off External Stimulator stimulation by turning on and off WT while over External Stimulator and then change settings. Turn Wireless Transmitter Power back on after changes have been made.
Action Not Available Cannot change External Stimulator Serial Number while Wireless Transmitters are assigned. Please unassign all Wireless Transmitters first. OK	User tries to change External Stimulator serial number in patient profile after authenticating one or more Wireless Transmitters to the assigned serial number (authentication is specific to a External Stimulator serial number so External Stimulator serial number cannot be changed without reauthenticating the Wireless Transmitter(s)).	Tap "OK" to close message. If External Stimulator serial number really does need to be changed, navigate to the WT management screen and unassign all Wireless Transmitters (see , page Error! Bookmark not defined.). Return to the Patient Profile screen to change External Stimulator serial number and then reassign Wireless Transmitters.
Therapy Error Please flip over the Wireless Transmitter to clear error. OK	Communication has been turned off or user tried to turn on Wireless Transmitter Power after removing Wireless Transmitter from charging pad without flipping the Wireless Transmitter over.	Tap "OK" to close message. Go to Info page and turn on Communication. or If the Wireless Transmitter was just removed from charging pad, flip over the Wireless Transmitter to turn on Wireless Transmitter Power.
Wireless Transmitter Alert - Battery level below 10% OK	Wireless Transmitter battery level is low.	Tap "OK" to close message. Charge Wireless Transmitter.

System Message	Cause	Resolution
Wireless Transmitter Alert - Wireless Transmitter temperature algorithm is non-functional OK	Wireless Transmitter control loop to monitor temperature has failed.	Tap "OK" to close message. Replace patient's Wireless Transmitter and return faulty unit to Neuspera.
Disconnected - Connection to Wireless Transmitter lost OK	Wireless Transmitter completely drained, turned off due to contact with a magnet, or moved out of range.	Ensure Wireless Transmitter is not near a magnet, is charged, and within range of the Clinician Programmer. If the issue continues, close the Clinician Programmer App, after a few minutes, restart Clinician Programmer App and try again.
Retrieval Failure Log file retrieval encountered an error. Data shown may not have been updated. OK	Communication between Clinician Programmer App and Wireless Transmitter interrupted.	Tap "OK" to close message. Ensure Clinician Programmer App is connected to the Wireless Transmitter. Switch to any other screen and then switch back to the Program Usage screen to update data.

14 TECHNICAL INFORMATION

14.1 System Physical and Performance Details

14.1.1 Trial Lead and Stylet

The Trial Lead and Stylet meet the following specifications:

Features	Material	Skin Contact Type & Duration (Days)
Packaging Tube & Clips	Polytetrafluoroethylene (PTFE)	Non-contact
Stylet Handle	Liquid Silicone Rubber	Non-contact
Stylet Assembly	304 Stainless Steel	Tissue contact < 24 hrs
Lead Conductor Wires	316 Stainless Steel	Tissue contact > 24 hrs, up to 7 days
Lead Insulation Material	Perfluoroalkoxy Alkanes (PFA)	Tissue contact > 24 hrs, up to 7 days
Lead Heat Shrink	PEBAX Polymer	Non-contact
Lead Proximal Pin	316 Stainless Steel	Non-contact

14.1.2 External Stimulator

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)

14.1.3 Wireless Transmitter (WT)

The technical specification for the Wireless Transmitter is as follows:

Battery capacity	≥2000mAh
Battery capacity (therapy time)	≥2 hours (will vary with RF power control settings)
Time for full recharge	≤5 hours
Maximum operating surface temperature	<60°C (140°F)
Frequency range (powering)*	902-928 (ISM compliant band)
Frequency range (Bluetooth)	2.4-2.5GHz
Water resistance	IP25 (Protected from touch by fingers and objects greater than 12 millimeters. Protected from low pressure water jets from any direction)

14.1.4 Wireless Transmitter Charging Pad

The Wireless Transmitter charging pad is an off-the-shelf Qi charging pad.

14.1.5 Operating, Storage, and Temperature 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)**
Clinician Programmer	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 requiring 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

14.1.6 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 system. Refer to the Neuspera Permanent System manuals for information on the shelf life of these components.

14.2 Disposal Guidance

- Follow local facility practices and policies for the return and disposal of devices as appropriate.

Caution:

- Follow appropriate biohazard material handling protocols for all explanted components or components coming into contact with bodily fluids. Only return such components to Neuspera in the appropriate packaging supplied by Neuspera.
- Do not reuse the Trial Lead, External Stimulator or accessories after exposure to body tissues or fluids because the sterility and functionality of the component cannot be guaranteed.

The Wireless Transmitter and Patient Controller contain lithium-ion batteries and must be disposed of according to local law.

14.3 Compliance

Full System	IEC 60601-1-2 and IEC 60601-4-2 (Group 2, Class B - Immunity for the home healthcare environment)
External Stimulator	IEC 60601-1 (Type BF Applied Part) IEC 60601-1-6 IEC 60601-1-11
Wireless Transmitter	IEC 60601-1 (Type BF Applied Part) IEC 60601-1-6 IEC 60601-1-11 IEC 62133-2 (battery)
Clinician Programmer and Patient Controller*	IEC 60950-1
Charging Pad*	FCC Part 15 Subpart C 15.209

**The hardware for the Clinician Programmer, Patient Controller and the Charging Pad are off-the-shelf consumer-grade information technology equipment and are being used in compliance with their intended use. Therefore, this hardware was not evaluated for compliance with IEC/ISO 60601-1 and biocompatibility (ISO 10993) when used according to these instructions.*

14.4 Wireless Technology Information

14.4.1 Quality of Service

The Neuspera Trial System uses wireless communication between the External Stimulator and Wireless Transmitter, and between the Wireless Transmitter and Apps.

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.

14.4.2 System Security

After the Trial Lead is implanted and External Stimulator is placed, the Wireless Transmitter will be uniquely paired to the External Stimulator and the Clinician Programmer and Patient Controller Apps.

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.

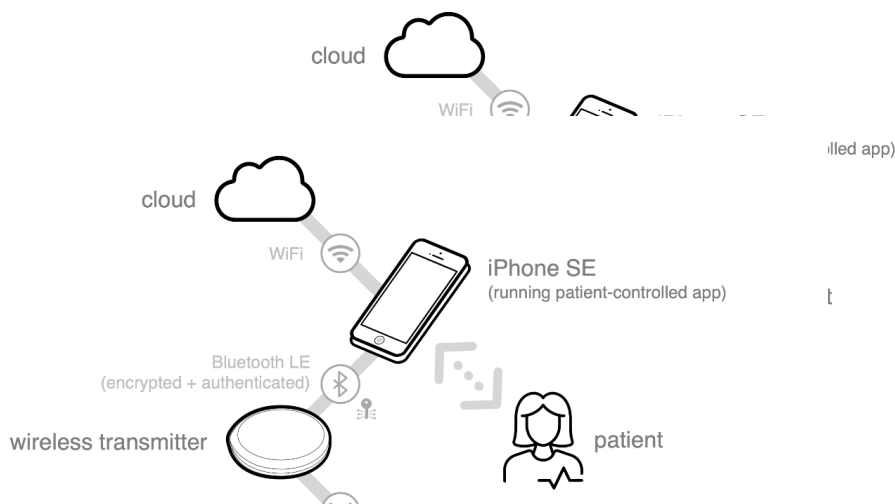


Figure 15. Schematic of authenticated connections/communications

14.4.3 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.

14.4.4 User Configurable Cybersecurity Controls

There are no installable or user alterable security controls.

14.4.5 Secure Configuration

An advanced cryptographically secure process is used to uniquely pair a patient's External Stimulator to a patient's Wireless Transmitter and the Wireless Transmitter to the Clinician Programmer and Patient Controller App. The Wireless Transmitter will only communicate with an authenticated paired App. 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 External Stimulator to ensure it only responds to the paired Wireless Transmitter.

14.4.6 Hardware, Software, Infrastructure Requirements

There are no local infrastructure requirements.

14.4.7 Authentication

A strong cryptographic challenge-response mechanism using symmetric cryptography has been implemented to authenticate each party. The Patient Controller and Clinician Programmer will each pair

through a different workflow of authorization. Patient Controllers must scan a generated barcode from a Clinician Programmer to pair to the Wireless Transmitter.

14.4.8 Network Ports

There are no network ports except the Wifi connections in the Clinician Programmer and Patient Controller.

14.4.9 Software Bill of Materials (SBOM)

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

14.4.10 Updating of Application and Device Firmware

When an update or a patch is available for the firmware or the Clinician Programmer App, a notification is sent to the clinician about the availability along with a link to download. Clinicians can then download the firmware or the App. No other action is needed by the clinician.

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.

14.4.11 Backup and Restore

No backup or restore function is provided.

14.4.12 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.

14.4.13 Log Files

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

14.4.14 Password requirements

The user is recommended to setup a password through the iOS operating system for the Clinician programmer and patient controller hardware.

14.4.15 End of Support

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

14.4.16 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 charging pad for several sessions such that all data is overwritten.

14.5 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.

14.6 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 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 | • Defibrillators |
| • Power substations | • PET therapy |
| • MR imagers | • Arc welders |
| • Cardiac devices | • Theft detections/screening devices |
| • Strong permanent magnets | • Plasma cutters |

Counsel patients to 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.

14.6.1 EMC-Related Precautions

- The Wireless Transmitter should not be used, and the Trial System and Trial Lead(s) should be removed from the patient prior to any electromagnetic medical investigation or treatment.
- Diathermy (shortwave, microwave, or therapeutic ultrasound) and radiofrequency ablation should not be used in the vicinity of the External Stimulator and Trial Lead(s) because these procedures have not been evaluated.
 - Therapeutic ultrasound should not be used in the area of the External Stimulator or Trial Lead(s) as the device can inadvertently concentrate the ultrasound field and cause harm.
 - Therapeutic ionizing radiation can damage the electrical components of the External Stimulator and any damage may not be immediately detectable.
- The Neuspera Trial 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.
- The Neuspera Trial System has not been tested for compatibility with cardiac defibrillation. Check the performance of the External Stimulator after defibrillation.

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)

14.6.2 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.

14.6.3 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.

14.6.4 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 19. Guidance and manufacturer's declaration – electromagnetic emissions

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF Emissions 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 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 20. 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 ±2 kV, ±4 kV, ±8 kV and ±15 kV air	±8 kV contact ±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 80 MHz to 2.7 GHz Refer to table 3 for wireless proximity RF field test levels	10 V/m <u>80 MHz to 2.7 GHz</u> Refer to table 3 for wireless proximity RF field test levels	
Radiated Fields in Close Proximity IEC 61000-4-39	8 A/m CW 65 A/m, Pulse modulation 2.1 kHz 7.5 A/m, Pulse modulation 50 kHz	8 A/m CW 65 A/m, Pulse modulation 2.1 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 21. 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 FRS 460	FM $\pm$ 5kHz deviation 1kHz Sine Wave	28	28
710 745 780	704 - 787	LTE Band 13 & 17	Pulse Modulation 217 Hz	9	9
810 870 930	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse Modulation 18Hz	28	28
1720 1845 1970	1700-1990	GSM 1800 CDMA 1900 DECT LTE Band 1,3,4,25, UMTS	Pulse Modulation 217 Hz	28	28
2450	2400-2570	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse Modulation 217 Hz	28	28
5240 5500 5785	5100 -5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	9	9



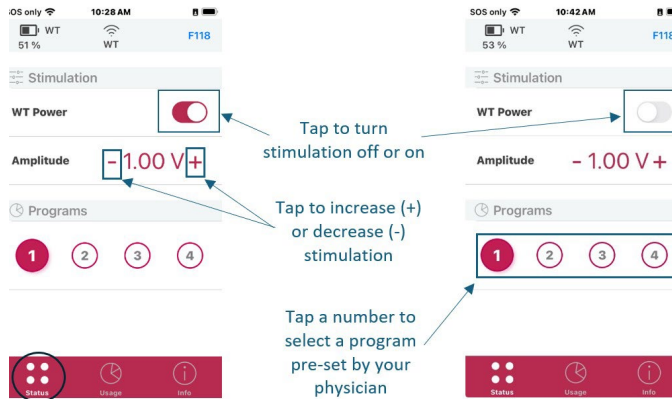
Neuspera Medical, Inc.
51 Daggett Drive
San Jose, CA 95134, USA
(888) 846-8332
www.neuspera.com

AFTER A THERAPY SESSION

1. Place your Wireless Transmitter on its charging pad to be charged and ready for your next session. Leave the Wireless Transmitter on the charging pad when it is not in use for a therapy/stimulation session.
2. The Undergarments can be machine washed and the Wireless Transmitter can be cleaned with a mild soap (like dish soap) and damp cloth. Please remember to remove the Wireless Transmitter before washing the Undergarment.

A FEW REMINDERS :

- Your Wireless Transmitter will turn on as soon as it is removed from the charging pad. If you are not putting it in the undergarment immediately, use your Patient Controller to turn it off.



- Do not lie on the Wireless Transmitter. The Wireless Transmitter should not be used while sleeping.
- The Wireless Transmitter will become warm during use. If it is uncomfortable to handle, turn stimulation off to let it cool down or remove the Wireless Transmitter by taking off your Undergarment.



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quick start guide

NEUSPERA SACRAL NEUROMODULATION SYSTEM

Please refer to your Patient Manual for more detailed information about your system.

PLEASE ENSURE YOU HAVE ALL ELEMENTS OF YOUR NEUSPERA SYSTEM:

- Wireless Transmitter
- Wireless Transmitter Charging Pad and Charging Cord
- Magnet
- Undergarments of the appropriate size
- Patient Controller and Charging Cord
- Patient ID Card – Keep it with you at all times.

PREPARING FOR A THERAPY SESSION

1. Make sure your Wireless Transmitter is charged.

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.

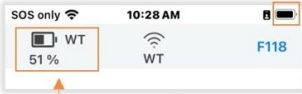
D. If charging has not started or there is an error indicated by the charging pad status light*, refer to the troubleshooting section.

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

2. Make sure your Patient Controller is charged.



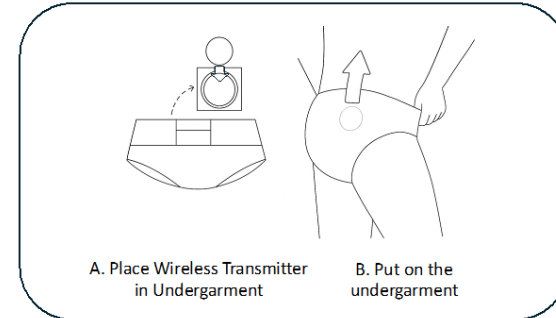
Port for charging cable



Controller battery level

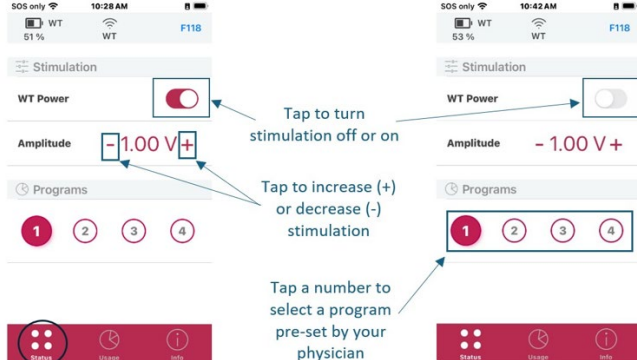
Wireless Transmitter battery level

3. Put Wireless Transmitter into Undergarment, making sure the dotted side of the Wireless Transmitter is facing your back.



4. 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.

5. If you do not feel stimulation, increase the amplitude on the Patient Controller. If changing the amplitude does not result in feeling stimulation, turn off stimulation, select different program, turn on stimulation, and repeat step 5.



Tap to turn stimulation off or on

Tap to increase (+) or decrease (-) stimulation

Tap a number to select a program pre-set by your physician

6. Once you can feel the stimulation and the setting is correct, you can begin your therapy session.

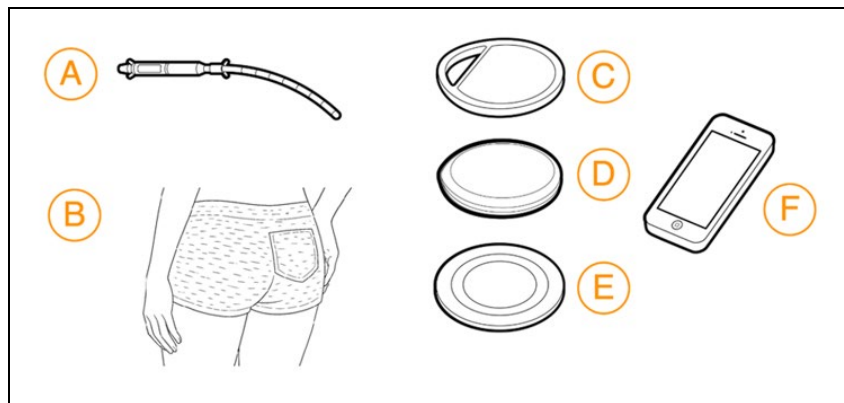


quick reference guide

**NEUSPERA SACRAL
NEUROMODULATION
SYSTEM**

Please refer to your Patient Manual for more detailed information about your system.

COMPONENTS OF YOUR SYSTEM



A. Implantable Neurostimulator, B. Undergarment, C. Magnet, D. Wireless Transmitter, E. Charging Pad, F. Patient Controller

BEFORE USE

1. Inspect the Wireless Transmitter for cracks, holes, or other damage and 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.

3. Your Wireless Transmitter should be at room temperature when you are using it. 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.
4. Charge the Wireless Transmitter (see figure below). Leave the Wireless Transmitter on the charging pad when it is not in use for a therapy/stimulation session. 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 in the undergarment immediately, use your App to turn it off.

- 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.

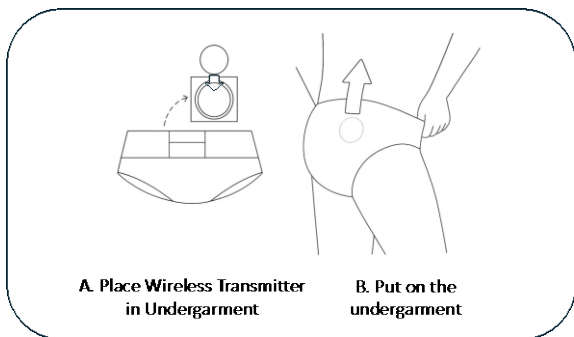
- C.** Confirm charging pad status light* indicates charging has started.
- D.** If charging has not started or there is an error indicated by the charging pad status light*, refer to the troubleshooting section.

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

administering a therapy session

PUTTING ON THE WIRELESS TRANSMITTER

Your Wireless Transmitter must be worn in the pocket of your Neuspéra Undergarment (see figure below). 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. It is normal for it to become warm during use. If it becomes uncomfortably hot, turn it off, take off your undergarment, and contact your physician/clinic.



STARTING A THERAPY SESSION

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. 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. If you still do not feel the tingling/pulling, increase the stimulation until you can feel it. If you still do not feel the tingling/pulling, check your App to confirm that the Wireless Transmitter battery is charged and stimulation is on and communication is on. Refer to the section “Your Patient Controller” in this guide to see how to perform these functions.

REMOVING THE WIRELESS TRANSMITTER/ENDING A THERAPY SESSION

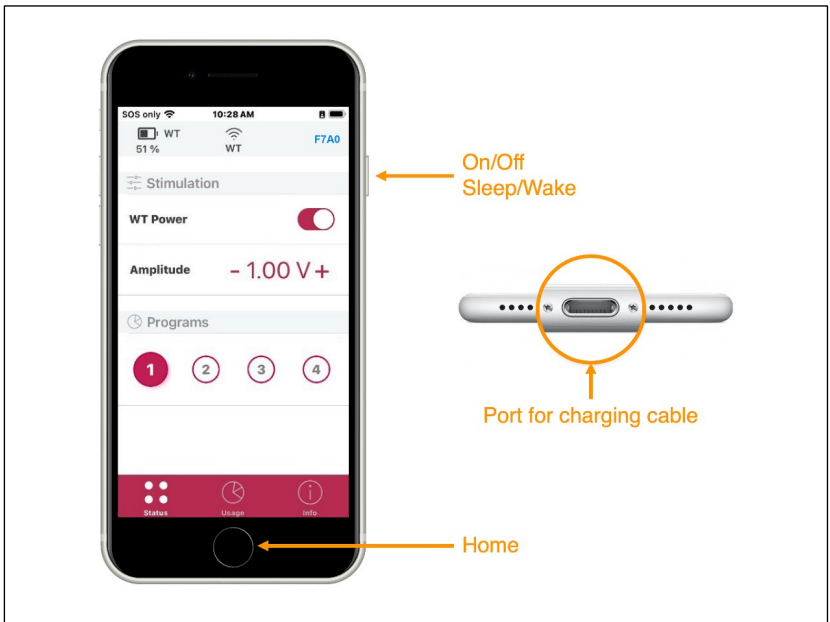
Stimulation stops when the Wireless Transmitter is removed from the area over your neurostimulator. Place the Wireless Transmitter on the charging pad after removal to ensure it is charged for its next use.

your patient controller

Note: Keep your Controller at least 10 centimeters (4 inches) away from your Wireless Transmitter when you are wearing your Wireless Transmitter. Your Controller may interfere with the communication between your Wireless Transmitter and neurostimulator.

CHARGING YOUR CONTROLLER

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



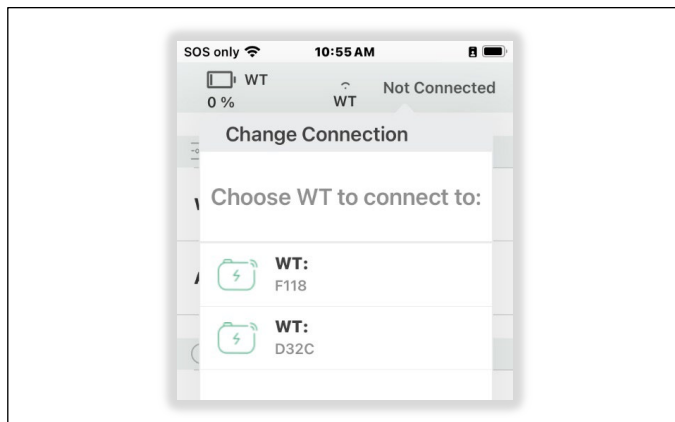
TURNING ON YOUR APP AND CONNECTING TO YOUR WIRELESS TRANSMITTER

1. Press the center “Home” button on the Controller to turn on the display. If the Controller is off, press and hold the top button to turn it on (see figure on Page 5).
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 below).

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

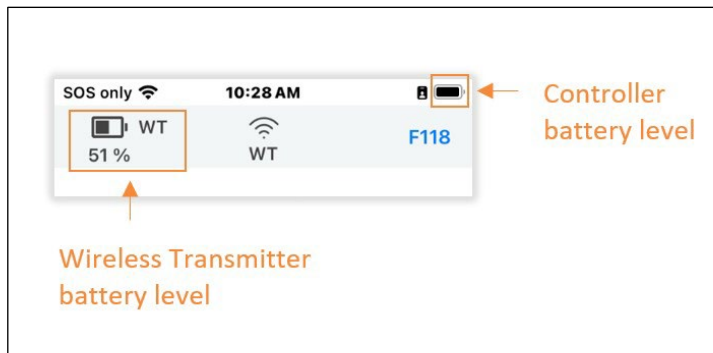


3. If the App shows that it is connected to a Wireless Transmitter other than the one you are wearing, tap the Wireless Transmitter ID in the upper right corner and select the correct Wireless Transmitter (see figure below).



CHECKING WIRELESS TRANSMITTER AND CONTROLLER BATTERY LEVELS

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

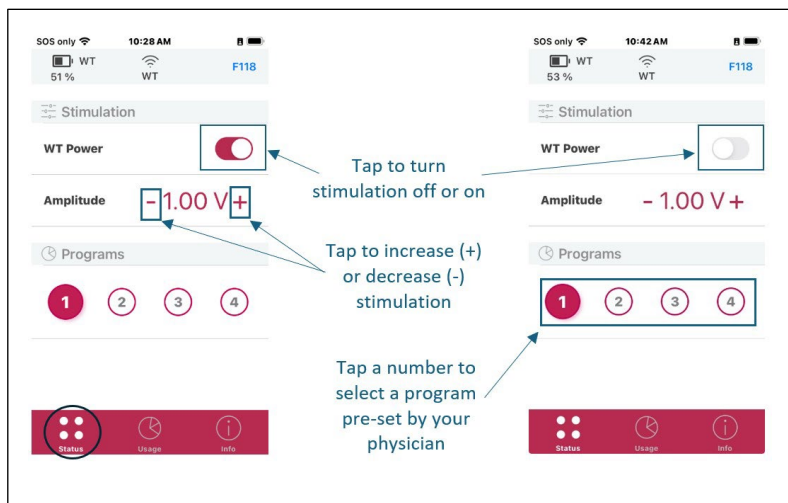


CHANGING STIMULATION SETTINGS

From the Status screen on your App, you can adjust your stimulation (see figure on page 8).

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 physician has set up for you. Turn stimulation off, select a different program (number), and turn stimulation back on. Consult with your physician 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.*



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.

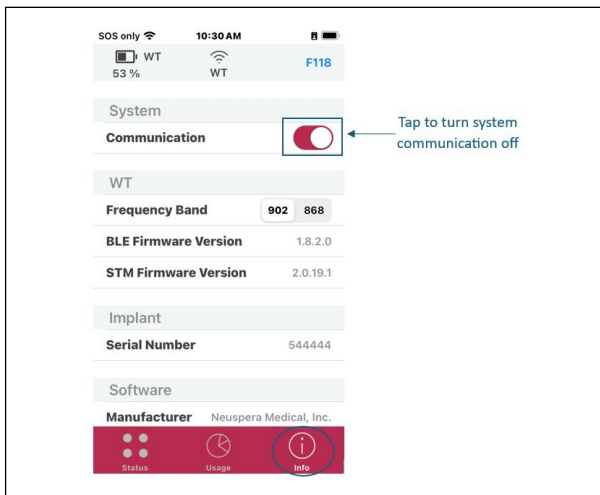
ADJUSTING YOUR WIRELESS TRANSMITTER AND CONTROLLER FOR TRAVEL

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

TURNING WIRELESS COMMUNICATION OFF

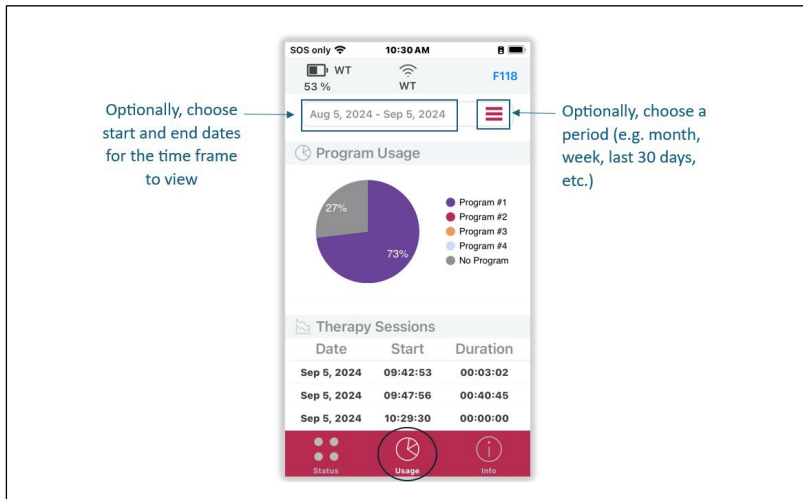
If your cell phone must be in airplane mode, the communications from your Wireless Transmitter and App must be turned off. First, switch your Controller to airplane mode, then go to the Info screen on your App and tap the Communication “switch” so it is in the off position (see figure at the top of page 9).

Note: When communication is turned off, your Wireless Transmitter will not power your neurostimulator. You must turn communication back on to restart stimulation (see figure at the top of page 9).



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 below).



care of your system

CLEANING THE WIRELESS TRANSMITTER

To clean your Wireless Transmitter, use a damp cloth and mild soap (such as liquid dish soap).

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

CLEANING THE NEUSPERA UNDERGARMENTS

For proper hygiene, it is recommended that you wash your 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.

Note: Ensure your Wireless Transmitter is removed prior to washing the undergarment.

CLEANING THE MAGNET, CHARGING PAD AND CONTROLLER

Use a soft, dry, lint-free cloth to clean the magnet, charging pad and 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.

PATIENT ACTIVITIES

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

- Avoid sexual activity

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

- Limit physical activities that may put stress on the Neurostimulator.
- Limit activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause component fracture or dislodgement.

During the SANS-UUI Phase II clinical study, some patients had devices that migrated due to not limiting physical activities after implant; these migrations generally occurred within the first six weeks following the implant procedure.

Device breakage or migration may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Examples of such activities include gymnastics, mountain biking, and other sports or equipment that involve the movements described above.

After being implanted with the Neuspera SNM System:

- Avoid strenuous physical activity that could cause Neurostimulator fracture or migration and which may result in loss of stimulation, intermittent stimulation, or pain at the Neurostimulator site.
- Avoid diving below 10 meters (33 feet) of water or entering hyperbaric chambers above 200kPa.
- Postural changes, and other activities may result in you perceiving an increase in stimulation which may be uncomfortable. Some have described this as a jolting or shocking sensation.
- Consider movements involved in any planned activity and take precaution to avoid putting undue stress on the Neurostimulator. For example, in activities such as skydiving, when the parachute opens, there can be a sudden jerking motion that occurs. This may cause a Neurostimulator dislodgement or fracture. A surgical procedure may be required to reposition or replace the Neurostimulator. Ask your clinician about strenuous activities in which you participate.

While stimulation is occurring:

- Do not wear the Wireless Transmitter to deliver therapy during activities that could be unsafe for you or others (e.g., driving or the use of dangerous equipment) if you were to receive an unexpected jolt or shock.
- Avoid taking substances that may impair your ability to feel the Wireless Transmitter getting too warm and to not sleep or use heavy clothing or blankets while using the Wireless Transmitter. This may increase the chance of being injured from the elevated Wireless Transmitter temperature.
- Do not wear the Wireless Transmitter during charging. The Wireless Transmitter may heat up while charging. The Wireless Transmitter cannot

stimulate while charging. If the WT needs to be charged, another WT may be worn in the Undergarment instead and used to activate the Neurostimulator.

- Metal surfaces (e.g., wall, chair back) against the Wireless Transmitter may temporarily interrupt therapy (stimulation).
- It is normal for the Wireless Transmitter to get warm during therapy. If the WT becomes uncomfortably hot, turn it off or remove it.

COMPONENT MANIPULATION

After being implanted with the Neuspera SNM System, refrain from receiving any form of spinal or pelvic manipulation in the area of the Neurostimulator by chiropractors as this may damage the Neurostimulator. This may result in Neurostimulator fracture or dislodgement which may result in loss of stimulation, intermittent stimulation, or pain at the Neurostimulator site.

After being implanted with the Neuspera SNM System, refrain from manipulating the Neurostimulator. Pushing on or rubbing the Neurostimulator site may cause Neurostimulator damage, dislodgement, uncomfortable stimulation or pain at the Neurostimulator site.

troubleshooting

Common problems and their resolutions are listed below. For more information, please reference the patient manual. If these actions do not solve the problem, please contact your physician/clinic.

TROUBLESHOOTING, CAUSES AND RESOLUTIONS

problem	potential cause	recommended action
Wireless Transmitter is not charging (light is not solid and the correct color) <i>*Note: The light is dim and may not be visible in bright lighting.</i>	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).
	Wireless Transmitter is not placed with the correct side down on charging pad	Make sure the dotted, white side is facing up and logo/label side is on the bottom.
	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 on page 3.
	Wireless Transmitter has been damaged (by physical shock, extreme temperatures, and/or water has leaked into device)	Contact your physician for a replacement Wireless Transmitter.

problem	potential cause	recommended action
Wireless Transmitter is not charging (light is not solid and the correct color)	Wireless Transmitter has become inoperative	Wireless Transmitter needs to be reset. 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 to perform reset. The teardrop point of the magnet should be aligned with the teardrop point of the Wireless Transmitter (see figure on page 18). After 5-10 seconds, remove magnet from Wireless Transmitter. Do not leave magnet on Wireless Transmitter while it is charging. Confirm reset was successful by observing the following: 1. Confirming the green light on the Wireless Transmitter is blinking. 2. Waiting 30 seconds and observing that the status light of the charging pad has initiated.
Controller is not charging	Charging cable not plugged in	Check that the charging cable is properly plugged into a powered outlet and into the Controller.
Controller display doesn't turn on	Controller is turned off	Turn Controller on by pressing button on top edge of device.
	Controller battery is extremely low	Charge Controller for at least 2 minutes and while still plugged in, turn 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 Controller are not close enough	Check that the Wireless Transmitter is within 1 meter (3 feet) of the Controller.
	Controller battery is too low	Check battery level on your App 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 physician/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 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.
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. 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
Wireless Transmitter stops working	Wireless Transmitter damaged by dropping or water or excessive moisture	Contact your physician/clinic for a new Wireless Transmitter.
	The Wireless Transmitter has become inoperative	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 to perform reset. The teardrop point of the magnet should be aligned with the teardrop point of the Wireless Transmitter (see figure on page 18). After 5-10 seconds, remove magnet from Wireless Transmitter. Do not leave magnet on Wireless Transmitter while it is charging. Confirm reset was successful by observing the following: 1. Confirming the green light on the Wireless Transmitter is blinking. 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 physician/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 physician.
Undergarment is uncomfortable	Incorrect size or worn incorrectly	Check that the label is on the inside and it is at the back. If the garment is still uncomfortable, contact your physician/clinic for other sizes.
Therapy is uncomfortable	Stimulation is too high	Decrease amplitude or change programs. If this does not resolve your discomfort, contact your physician/clinic.
Therapy is not felt	Stimulation is too low	Increase amplitude or change programs.
	Wireless Transmitter is not connecting to your neurostimulator	See below.

problem	potential cause	recommended action
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.
	Wireless Transmitter battery is too low	Check battery level from your App. 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". 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 physician/clinic for a replacement Wireless Transmitter.

APP MESSAGES, CAUSES, AND RESOLUTIONS

system message	cause	resolution
Action Not Available Cannot change settings while Therapy is active OK	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.
Therapy Error Please flip over the WT to clear error. OK	User tried to turn on WT Power while communication has been turned off or User tried to turn on WT Power after removing WT from charger without flipping WT over.	Tap "OK" to close message. Go to Info page and turn on Communication. or If the WT was just removed from charger, flip over the WT to turn on WT Power.
WT Alert Battery level below 10% OK	Wireless Transmitter battery is getting low.	Tap "OK" to close message. Return Wireless Transmitter to the charging pad.
Connection Failed Connecting to the WT failed, please ensure that the WT is in range and tap yes to try to connect again. NO YES	Controller does not detect Wireless Transmitter signal	Ensure Wireless Transmitter and 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 OK	Controller does not detect Wireless Transmitter signal (2 nd message if still cannot connect after above message)	Check battery level from your App. Charge Wireless Transmitter if battery is low.

system message	cause	resolution
WT Alert WT temperature algorithm is non-functional OK	Wireless Transmitter temperature control is not working.	Tap "OK" to close message. Discontinue use. Contact your physician/clinic for a new Wireless Transmitter.
Disconnected The connection to the WT was lost, would you like to reconnect? NO YES	Wireless Transmitter completely drained, turned off due to contact with a magnet, or moved out of range	Ensure Wireless Transmitter is: • Not near a magnet • Charged • Within range (1 meter or 3 feet) of the Controller Click "Yes" to reconnect. If the issue continues, close the App, after a few minutes, restart App and try again.
Retrieval Failure Log file retrieval encountered an error. Data shown may not have been updated. OK	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.
Confirm Delete Are you sure you want to delete all registered WT's? NO YES	User has selected "Delete All Connections."	Tap "No" to exit the message. <i>Note: Only your physician or clinic representative, at your physician's direction, should delete the Wireless Transmitter from your App.</i>
	No Wireless Transmitters are linked to your App.	Contact your physician/clinic.

Please refer to your Patient Manual for more detailed information about your system or ask your doctor/clinic for assistance.