

# Study to collect long-term clinical data for the recharge free Axonics SNM System (INS Model 4101)

<b>Submission date</b> 23/05/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/05/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/10/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of the study is to obtain long-term clinical data for the recharge-free Axonics F15 SNM System (also referred to as INS Model 4101).

### Who can participate?

Adults aged 18 or older, previously diagnosed with urinary urge incontinence (UUI) with or without urinary frequency (UF) and/or chronic fecal incontinence (FI), who received the Axonics F15 SNM System device and who have baseline bladder or bowel diaries.

### What does the study involve?

The study involves a retrospective chart review of all F15 implants that took place  $\geq 1$ -year post-implant, at selected centers. In addition, patients who have baseline bladder or bowel diaries will be prospectively enrolled and will complete one follow-up visit. The follow-up visit entails completing a post-operative bladder or bowel diary and a patient satisfaction questionnaire.

### What are the possible benefits and risks of participating?

**Benefit:** The study will help gather long-term data on the recharge-free Axonics F15 SNM System (also referred to as INS Model 4101).

**Risks:** Similar to any sacral neuromodulation device indicated for overactive bladder disease and fecal incontinence.

### Where is the study run from?

Axonics, Inc. (USA)

### When is the study starting and how long is it expected to run for?

December 2023 to June 2025

### Who is funding the study?

Axonics, Inc. (USA)

Who is the main contact?  
Dr Karen Noblett, karen.noblett@bsci.com

## Contact information

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Scientific

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## Additional identifiers

## **Clinical Trials Information System (CTIS)**

Nil known

## **ClinicalTrials.gov (NCT)**

Nil known

## **Protocol serial number**

105-0118

# **Study information**

## **Scientific Title**

F15 follow-up study

## **Study objectives**

To obtain long-term clinical data for the recharge free Axonics F15 SNM System (also referred to as INS Model 4101).

## **Ethics approval required**

Ethics approval not required

## **Ethics approval(s)**

The study is a data collection effort whereby data is being collected retrospectively from those patients who were implanted with the Axonics SNM F15 device who are  $\geq$  1-year post-implant and who have baseline bladder or bowel diaries. Please note the device has been approved by the Food and Drug Administration (FDA) in the United States and Canada in 2022 and recently approved by the Therapeutic Goods Administration (TGA) in Australia in 2024.

## **Study design**

Observational cohort study

## **Primary study design**

Observational

## **Study type(s)**

Other, Quality of life

## **Health condition(s) or problem(s) studied**

Urinary urge incontinence (UUI) with or without urinary frequency (UF) and/or chronic fecal incontinence (FI)

## **Interventions**

Multicenter, prospective study comparing bladder or bowel diaries at baseline to a minimum of 1 year follow up and up to 2 years if the participant is eligible (i.e., participants implanted between March/July 2022). Participants will be identified through a retrospective chart review of all patients at the selected sites who were implanted with the Axonics F15 SNM and who have baseline bladder or bowel diaries. Device parameters and safety data will be collected, and a patient satisfaction questionnaire will be administered at the followup visit.

## **Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Axonics F15 SNM System (also referred to as INS Model 4101)

**Primary outcome(s)**

Comparison from baseline to follow-up for the following:

1.  $\geq 50\%$  reduction in UUI episodes per day on a 3-day bladder diary OR
2.  $\geq 50\%$  reduction in FI episodes on a minimum of 5-day bowel diary

**Key secondary outcome(s)**

Comparison from baseline to follow-up for the following:

1. Complete urinary or fecal continence measured using a bladder or bowel diary
2. Device parameters (programming settings, impedance values) measured using the Clinician Programmer (CP), a tablet computer used by the clinician (or sponsor representative) to wirelessly communicate with the neurostimulator to check the device status and/or program the device
3. Procedure and/or device-related adverse events as reported in source documents by the physician and/or research staff
4. Serious adverse events (SAEs) as reported in source documents by the physician and/or research staff
5. Patient satisfaction measured using a Patient Satisfaction Questionnaire

**Completion date**

25/06/2025

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 27/06/2025:

1. Aged 18 years or older
2. Provides written informed consent
3. Primary indication of UUI (with or without UF) or chronic FI who failed or could not tolerate more conservative treatments and implanted with the Axonics F15 SNM System and who have reached 1-year or greater, post-implant
4. Completion of a baseline pre-PNE 3-day bladder diary for UUI or a minimum of 5-day pre-PNE bowel diary for FI

Previous inclusion criteria:

1. Aged 18 years or older
2. Provides written informed consent
3. Primary indication of UUI (with or without UF) or chronic FI who failed or could not tolerate more conservative treatments and implanted with the Axonics F15 SNM System and who have reached 1-year or greater, post-implant
4. Completion of a baseline pre-PNE 3-day bladder diary for UUI or a minimum of 7-day pre-PNE bowel diary for FI
5. English speaking

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

69

**Key exclusion criteria**

1. Any significant medical condition that is likely to interfere with trial procedures, device operation, or likely to confound evaluation of trial endpoints (i.e., exclusion of neurological conditions such as multiple sclerosis)
2. Any psychiatric or personality disorder that is likely to interfere with trial procedures at the discretion of the participating physician; this may include poor understanding or compliance with trial requirements
3. A female who is breastfeeding
4. A female with a positive urine pregnancy test
5. Intradetrusor chemodenevation with OnabotulinumtoxinA (Botox) injections within 6 months prior to study follow-up visit
6. Prior history of pelvic or rectal cancer
7. Prior history of pelvic radiation

**Date of first enrolment**

27/03/2024

**Date of final enrolment**

22/04/2025

**Locations****Countries of recruitment**

United States of America

**Study participating centre**

**Florida Bladder Institute**

1890 SW Health Parkway, Suite 205

Naples  
United States of America  
FL 34109

**Study participating centre**  
**University of Cincinnati**  
51 Goodman Drive, Suite 530  
Cincinnati  
United States of America  
Ohio 45221

**Study participating centre**  
**Urologic Solutions LLC**  
9400 Gladiolus Drive, Suite 30  
Fort Myers  
United States of America  
FL 33908

**Study participating centre**  
**Southern Urogynecology**  
115 Midlands Court  
West Columbia  
United States of America  
SC 29169

**Study participating centre**  
**Nevada Surgical**  
5500 Reno Corporate Drive  
Reno  
United States of America  
NV 89511

**Study participating centre**  
**Urology Associates**  
134 Hoyle Avenue  
Fairhope  
United States of America  
AL 36532

**Study participating centre**  
**Female Pelvic Health Center**  
760 Newtown Yardley Road  
Suite 115  
Newtown  
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PA 18940

**Study participating centre**  
**Urology San Antonio**  
7909 Fredericksburg Road  
Suite 110  
San Antonio  
United States of America  
TX 78229

## Sponsor information

**Organisation**  
Axonics, Inc.

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Axonics, Inc.

## Results and Publications

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository called Medrio. Contact: Heather Waldeck, PhD (heather.waldeck@bsci.com)

Data will be made available in the form of a published manuscript in a peer-reviewed journal. The estimated time frame is August 2025.

### **IPD sharing plan summary**

Stored in non-publicly available repository, Published as a supplement to the results publication

**Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Other unpublished results</a>		21/07/2025	01/10/2025	No	No
<a href="#">Protocol file</a>		15/05/2024	01/10/2025	No	No