

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

Submission date 23/05/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/05/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/07/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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 ≥ 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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

GP practice, Hospital, Medical and other records

Study type(s)

Other, Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participation information sheet.

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

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

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

18/12/2023

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

Up to 80

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 chemodenervation 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
United States of America
PA 18940

Study participating centre
Urology San Antonio
7909 Fredericksburg Road
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Sponsor type
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Funder(s)

Funder type
Industry

Funder Name
Axonics, Inc.

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
30/09/2025

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