3. PROTOCOL SYNOPSIS

Title:	Sacral Neuromodulation for **M**ale **O**ver**A**ctive **B**ladder **(MOAB)** Study
Protocol Number	105-0141
Study Sponsor:	Axonics / Boston Scientific Corporation 15515 Sand Canyon Avenue Irvine, CA 92618 Contact: Gita Ghadimi, OD Email: gita.ghadimi@bsci.com Tel. +1 949.981.4366 www.axonics.com
Trial Device:	Axonics SNM System (INS Model 4101 [F15] and INS Model 5101 [R20])
Indications For Use:	**Axonics Sacral Neuromodulation (SNM) System for Urinary Control** Axonics SNM Therapy for urinary control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urgency incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.
Study Objective:	To assess the post-market clinical outcomes with use of the Axonics Sacral Neuromodulation System(s) for the treatment of overactive bladder in male patients who have a prior history of radical prostatectomy or radiation for prostate cancer or who have a history of cytoreductive surgical intervention for benign prostatic hyperplasia (BPH).
Study Design:	Multicenter, prospective, non-randomized, single arm study with up to 150 male participants (50 per group) with a primary indication of OAB (UUI or UF) will be enrolled and implanted for each of the following 3 groups: 1. Patients with a history of radical prostatectomy for prostate cancer ("Post-Prostatectomy" group) 2. Patients with history of radiation therapy for prostate cancer ("Radiation" group) 3. Patients with a history of cytoreductive surgical intervention for Benign Prostatic Hyperplasia (BPH) ("BPH" group)
Study Sites:	Up to 150 participants (and up to 50 for each group) will be enrolled and implanted at up to 30 participating centers in the United States. Sites are selected based on their experience in conducting clinical trials, their experience implanting the Axonics SNM System, as well as their ability to maintain robust enrollment and follow-up.

Study Duration:

This clinical study begins with the enrollment of the first participant and ends after the last participant exits the study. The study will be officially closed once all participants have been monitored, all outstanding data queries have been resolved and all sites are closed upon notification and acknowledgement by the Institutional Review Board (IRB). The enrollment period will be approximately 24 months. The study duration is expected to be approximately 36 months from the start of study enrollment. Participants will be active in the study for 1 year post INS implant.

Study Population:

Male adults aged 18 or older, diagnosed with overactive bladder (OAB) including urinary urgency incontinence (UUI) and/or urinary frequency (UF).

Study Visits:

Visit	Visit Window
Baseline	---
Implant/Device Activation[1]	Day 0
1-4 Week[2]	Day 3-31
6-Month	Day 180 ± 30 (Day 150-210)
12-Month	Day 365 ± 60 (Day 305-425)
Study Exit	---

[1] Includes implant and INS activation (*Note:* there may be cases where activation occurs on a different day than implant; if this occurs Day 0 will be considered the date of activation.)

[2] After Day 0 per site's standard of care

Outcome Measures:

For Safety:

Rate of device-related and procedure-related adverse events

Rate of Serious Adverse Events (SAEs)

***For Effectiveness/Performance*:**

- Change in Quality-of-life questionnaires: International Consultation on Incontinence Questionnaire Overactive Bladder quality of life (ICIQ-OABqol) at 6-month and 1-year compared to baseline
- Participant Satisfaction Questionnaire
- Demonstrate a ≥ 50% reduction in the number of average daily OAB episodes on a 3-day diary at 6-months and 1-year compared to baseline

Enrollment:

Inclusion criteria:

For all participants:

1. Willing and capable of providing informed consent
2. Participants aged ≥ 18 years at the time of enrollment
3. Able to complete bladder diaries and all required patient questionnaires
4. Patients scheduled to be trialed with the Axonics External Trial System (ETS)
5. Primary diagnosis of OAB (UUI and/or UF). UUI defined as a minimum of at least three leaks associated with urgency as demonstrated on a 72-

hour bladder diary. UF defined as an average of at least 8 voids per 24 hours as demonstrated on a 72-hour bladder diary.

6. Failed conservative therapy and second-line drug therapy and is not a candidate for additional conservative or second-line therapy
7. Post-void residual volume <200 cc within the last 6 months at the time of enrollment
8. Stated willingness and capability to comply with all study procedures and availability to return to site for all study visits for the duration of the study

Patients in the Post-Prostatectomy group:

9. Underwent a radical prostatectomy procedure at least 6 months prior to enrollment

Patients in the Radiation group:

10. Underwent radiation therapy at least 6 months prior to enrollment

Patients in the Benign Prostatic Hyperplasia (BPH) group:

11. Underwent FDA approved BPH cytoreductive surgical intervention (including simple prostatectomy) at least 6 months prior to enrollment
12. International Prostate Symptom Score (IPSS)* score of ≤ 11 for the Benign Prostatic Hyperplasia (BPH) group

* Note: The total score is based on only questions 3 (intermittency), 5 (weak stream) and 6 (straining) on the International Prostate Symptom Score (IPSS).

Exclusion criteria:

A participant meeting any of the following criteria shall be excluded:

1. Any patient that is not a suitable study participant per investigator discretion
2. A prostate therapy or procedure within the last 6 months at the time of enrollment
3. Primary stress incontinence or mixed incontinence where the stress component overrides the urgency component
4. Any neurological condition that could interfere with normal bladder function, including stroke, epilepsy, multiple sclerosis, Parkinson's disease, clinically significant peripheral neuropathy, or spinal cord injury (e.g., paraplegia)
5. Previously implanted with a sacral neuromodulation device, including inactive SNM devices
6. Any prior treatment with an Implantable Tibial Nerve Stimulation (ITNS)
7. Positive response to Percutaneous Tibial Nerve Stimulation (PTNS) within the last 3 months at the time of enrollment
8. Underwent an external trial with any sacral neuromodulation device and was deemed a non-responder by a physician

9. Any significant medical condition that is likely to interfere with study procedures, device operation, or likely to confound evaluation of study objectives at the discretion of the participating physician
10. Uncontrolled diabetes (HbA1C> 8, documented in the last 3 months, for known diabetics only)
11. Any psychiatric or personality disorder that is likely to interfere with trial procedures at the discretion of the participating physician
12. Known allergic reactions to components of the Axonics SNM System, including titanium, zirconia, polyurethane, epoxy, or silicone
13. Current urinary tract mechanical obstruction (e.g. benign prostatic enlargement or urethral stricture)
14. Current symptomatic urinary tract infection (UTI) or history of > 3 UTIs in the past 12 months or > 2 UTIs in the past 6 months
15. Treatment of urinary symptoms with intravesical botulinum toxin therapy within 9 months prior to consent

Patients in the Radiation group:

16. History of a radical prostatectomy

Patients in the Benign Prostatic Hyperplasia (BPH) group:

17. History of a radical prostatectomy and/or prostate radiation therapy

Data Collection:

Visits will require the participant to be on-site due to electronic data collection methods and/or assessment of the device for the 6-month and 12-month study endpoints. Check-in calls and other study-related activities (specified by the clinical site) may be conducted remotely by the site (e.g.; eConsent if site(s) uses this platform, administration of questionnaires). Adverse events will be reported by the Investigator and or his/her designee through completion of the applicable case report form (CRF) or electronic case report form (eCRF).

The EDC system used for this study will be a validated database application (or equivalent) on a central server that is 21 CFR Part 11 compliant. The application provides the capability of data collection remotely through the internet so the participating site personnel and/or the participants may log on to the system securely and enter the data.

Device Status: INS Models 4101 (F15) and 5101 (R20) are approved in the United States

4. ABBREVIATIONS

Acronym	Definition
ADE	Adverse Device Event
AE	Adverse Event