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ORIGINAL CLINICAL ARTICLE

Two-year safety and efficacy outcomes for the treatment of overactive bladder using a long-lived rechargeable sacral neuromodulation system

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Abstract

Aims: Sacral neuromodulation (SNM) therapy for overactive bladder (OAB) has proven long-term safety and efficacy. Historically, the only commercially available SNM device was nonrechargeable requiring replacement surgery due to battery depletion. The Axonics System is the first rechargeable SNM device and is qualified to last a minimum of 15 years in the body. The study objective was to evaluate the safety and efficacy of this rechargeable SNM system. This study reports 2-year outcomes.

Methods: A total of 51 subjects were implanted with the Axonics System in a single nonstaged procedure. Subjects had OAB, confirmed on a 3-day voiding diary (≥8 voids/day and/or ≥2 incontinence episodes over 72 hours). Test Responders were defined as subjects that were responders at 1 month post-implant. The efficacy analysis included therapy responder rates, change in the quality of life, and subject satisfaction reported in Test Responders (n = 30) and all implanted subjects (n = 37) that completed the follow-up visits. Adverse events (AEs) are reported in all implanted subjects.

Results: At 2 years, 90% of the Test Responders continued to respond to the therapy based on voiding diary criteria. Satisfaction with therapy was reported by 93% of subjects and 86% found their charging experience acceptable. Of the urinary incontinence Test Responders, 88% continued to be responders at 2 years, and 28% were completely dry. There were no unanticipated (AEs) or serious device-related AEs.

Conclusions: The Axonics System® provides sustained clinically meaningful improvements in OAB subjects at 2 years. There were no serious device-related AEs. Subjects reported continued satisfaction with their therapy.

KEYWORDS

overactive bladder, rechargeable, sacral neuromodulation, single-stage implant, urgency frequency, urinary incontinence

1 | INTRODUCTION

The European Association of Urology, the American Urological Association, and the Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction, all identify sacral neuromodulation (SNM) as a guideline approved treatment for refractory overactive bladder (OAB) symptoms.[1,2] SNM received CE mark for urinary dysfunction and fecal incontinence in 1994.[3] In the United States, the Food and Drug Administration (FDA) approved SNM therapy for the treatment of urgency incontinence in 1997 and then in 1999 approved the therapy for urgency frequency and urinary retention. SNM was approved by the FDA for treatment of fecal incontinence in 2011. To date, more than 325 000 patients worldwide have been treated with SNM therapy;[4–7] however, the addressable population with these conditions is significantly underpenetrated.

Historically, the only commercially available SNM product was a nonrechargeable, voltage-controlled neurostimulator, which required replacement surgeries due to battery depletion. Since OAB is a chronic condition, multiple device replacements would be required over the lifetime of the patient to manage their condition. Replacement surgeries are burdensome and expose patients to surgical risks and increase the financial impact to the healthcare system. A long-lived SNM device can significantly reduce, and potentially eliminate the need for replacement surgeries, thereby improving the long-term safety and cost-effectiveness of this therapy.[8]

The Axonics System is a miniaturized rechargeable SNM system designed and approved to last for a minimum of 15 years in the body. This system has regulatory approval in the United States, Europe (CE mark), Canada, and Australia. The RELAX-OAB study was a postmarket prospective clinical follow-up study in Europe designed to test the safety and efficacy of the Axonics System up to 2 years. A favorable clinical safety and efficacy profile of the Axonics System has been reported up to 12 months.[9–11] Two-year safety and efficacy outcomes of the RELAX-OAB study are presented here.

2 | METHODS

2.1 | Study overview

The study protocol was approved by Ethics Committees at all centers. All subjects reviewed and signed informed consent before study enrollment.

Details of the study design, inclusion and exclusion (IE) criteria, implant procedure, and data analysis have been published previously.[9,10] The primary diagnosis of OAB was confirmed on a 3-day voiding diary as ≥8 voids per day and/or a minimum of two urinary incontinence (UI) episodes over 3 days.

Subjects that met all IE criteria were implanted with the Axonics System in a single nonstaged procedure, without being screened by an external test/trial system. A "Test Period" of 1 month was simulated, and therapy response at the 2-week and 1-month follow-up visits were used to evaluate whether subjects were "Test Responders" or "Test Failures." A responder was defined as having a ≥50% reduction in voids or UI episodes (leaks) or a reduction to <8 voids per day. Test Responders were subjects that were responders at the 2-week or 1-month follow-up visit.

Postoperatively, study subjects were instructed to charge their neurostimulator every 1 to 2 weeks. Charging is performed using a wireless charging device that is placed on the skin over the implanted neurostimulator and held in place using a belt.

The primary data analyses are performed in Test Responders to be comparable with the cohort in the clinical literature. Data analysis was also performed in all implanted subjects with data available at 2 years ("All implanted subjects"). All efficacy analyses were performed in the completers group (ie, only subjects available at follow-up were included). Subjects with major protocol deviations were not included in the efficacy analyses.

Absolute and percent change was calculated for leaks, large leaks, voids, and severe and desperate urgency episodes. Subject quality of life and satisfaction with therapy were evaluated using the validated International Consultation on Incontinence Modular Questionnaire (ICIQ-OABqol) and a subject satisfaction questionnaire, respectively.

Adverse events (AEs) were reviewed and adjudicated by a Data Safety Monitoring Board consisting of three independent clinicians. Statistical significance testing was performed using the Wilcoxon signed-rank test or two-tailed t test for continuous variables or Fisher's exact test for categorical variables. The software package SAS (v 9.1) was used.

3 | RESULTS

3.1 | Subject demographics and disposition

A total of 51 subjects (38 females and 13 males) with an average age of 51 years old (21-77 years old) were implanted with the Axonics System. A total of 50 of

the 51 subjects (98%) had urinary frequency (UF), and 37 (73%) had UI. The average baseline voids per day in the UF population was 14.7 (±0.9, standard error), and average leaks per day in the UI population was 9.6 (±0.8). Of the 51 implanted subjects, 51% were previously treated with other third line OAB therapy including percutaneous tibial nerve stimulation and/or OnabotulinumtoxinA (Botox) intradetrusor injections. Detailed baseline demographics have been published previously.[9]

As previously reported,[9] 34 of the 48 (71%) per protocol subjects were Test Responders at the end of the 1-month test period, of which 28 subjects had UI and 33 subjects had UF. The remaining three subjects (of 51 implanted) were not included in the per protocol analysis, because two subjects had a missing baseline diary, and one subject was explanted at 2 weeks due to infection at the neurostimulator site.

Of the 51 implanted subjects, 40 subjects completed the 2-year follow-up visit, of which 38 had no major protocol deviations, and 37 had a complete diary. A total of 30 of the 34 Test Responders completed the 2-year visit without any major protocol deviations.

The following subjects were excluded from the analysis: two subjects with incomplete baseline diaries, four subjects that were lost to follow-up or voluntarily withdrew from the study (two of these were Test Responders), and seven explanted subjects (two of which were Test Responders) (details provided later). One subject, a Test Failure, did not complete a 2-year diary and is excluded from the "all implanted subjects" diary analysis at 2 years.

3.2 | Two-year outcomes

3.2.1 | Therapy response in Test Responders

At 2 years, 90% of the Test Responders (27/30) continued to respond to therapy (Figure 1).

Urinary incontinence

Of the UI Test Responders, 88% were responders (22/25) (Figure 1) on their UI symptoms. Forty-eight percent of the subjects had ≥90% reduction in leaks and 28% of the subjects were completely dry.

Leaks per day reduced from an average of 8.3 (±0.8) at baseline to 1.7 (±0.5) at 2 years, an 80% reduction in leaks ($P < .0001$; two-sided t test; n = 25) (Figure 2A). Large leaks per day decreased from an average baseline of 2.5 (±0.7) to 0.3 (±0.1) at 2 years (n = 19) (Figure 2A).

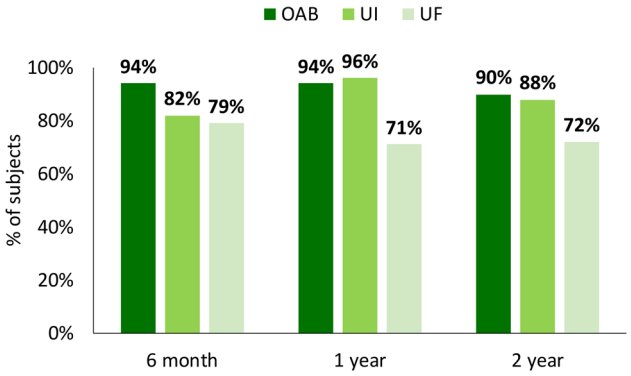

FIGURE 1 Long-term therapy responder rates in Test Responders out to 2 years. OAB therapy response was determined by a ≥50% reduction in voids or all leaks or a return to normal voiding frequency (≤8 voids per day). UI therapy response was determined by a ≥50% reduction in all leaks, and UF therapy response was determined by a ≥50% reduction in voids or a return to normal voiding frequency (≤8 voids per day). Per protocol analysis is presented. OAB, overactive bladder; UF, urinary frequency; UI, urinary incontinence

A total of 16 of 19 subjects (84%) had ≥50% reduction in large leaks, of which 79% of subjects (15/19) had a 100% reduction in large leaks.

Urinary frequency

Of the 29 UF Test Responders, 21 (72%) were responders on their UF symptoms (less than eight voids or a ≥50% reduction in voids as compared to baseline) at the 2-year visit (Figure 1).

Voids per day reduced from 14.3 (±1.1) voids on average at baseline to 7.3 (±0.4) at 2 years ($P < .0001$; two-sided t test) (Figure 2B). Severe and desperate urgency episodes per day at 2 years decreased to 2.2 (±0.5) as compared to a baseline average of 7.5 (±1.2) (Figure 2B). Severe and desperate urgency episodes were reduced by ≥50% in 76% of subjects (22/29).

Quality of life

Test Responders had clinically meaningful improvements in quality of life, defined as at least a 10 point increase in the ICIQ-OABqol health-related quality of life (HRQL) score.[4,12] The average paired change in the HRQL score in Test Responders was an improvement of 29 points ($P < .0001$; n = 28) (Figure 3A). Each of the four ICIQ-OABqol subscales (concern, coping, sleep, and social interaction) also showed statistically and clinically significant improvements ($P < .0001$).

Subject satisfaction and charging experience

Subject satisfaction at 2 years is shown in Figure 3. Of the Test Responders, 93% were satisfied with their therapy

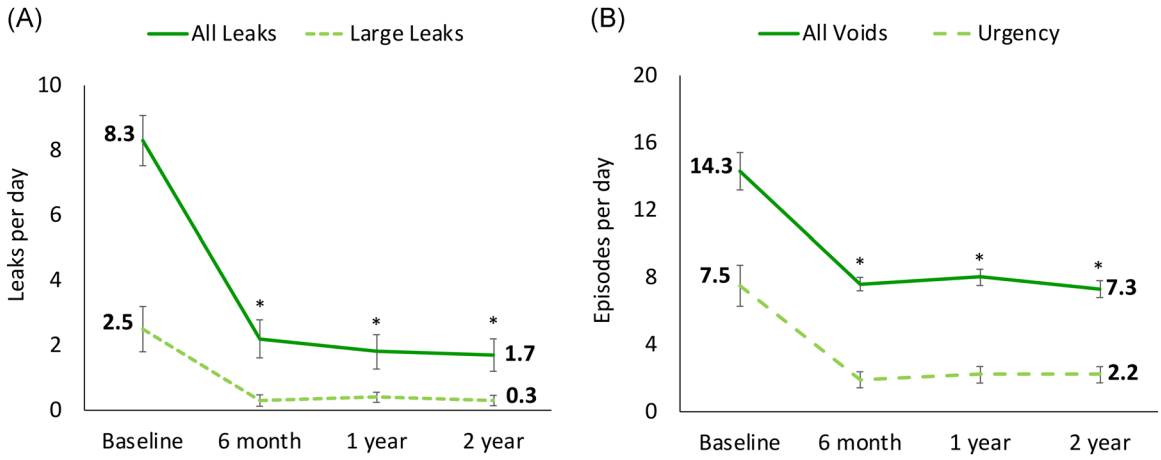

FIGURE 2 Symptom reduction in Test Responders. Average and standard error at baseline, 6-month, 1-year, and 2-year visits for (A) All leaks and large leaks and for (B) voids and severe and desperate urgency episodes. *$P < .0001$ compared to baseline

(Figure 3B) and 90% reported that they would definitely or probably recommend the therapy to friends.

With regard to the charging experience, 86% of subjects reported that the duration and frequency of charging their system were acceptable (Figure 3C).

3.2.2 | Therapy response in all implanted subjects

At 2 years, 76% of all implanted subjects available for follow-up (28/37) were therapy responders.

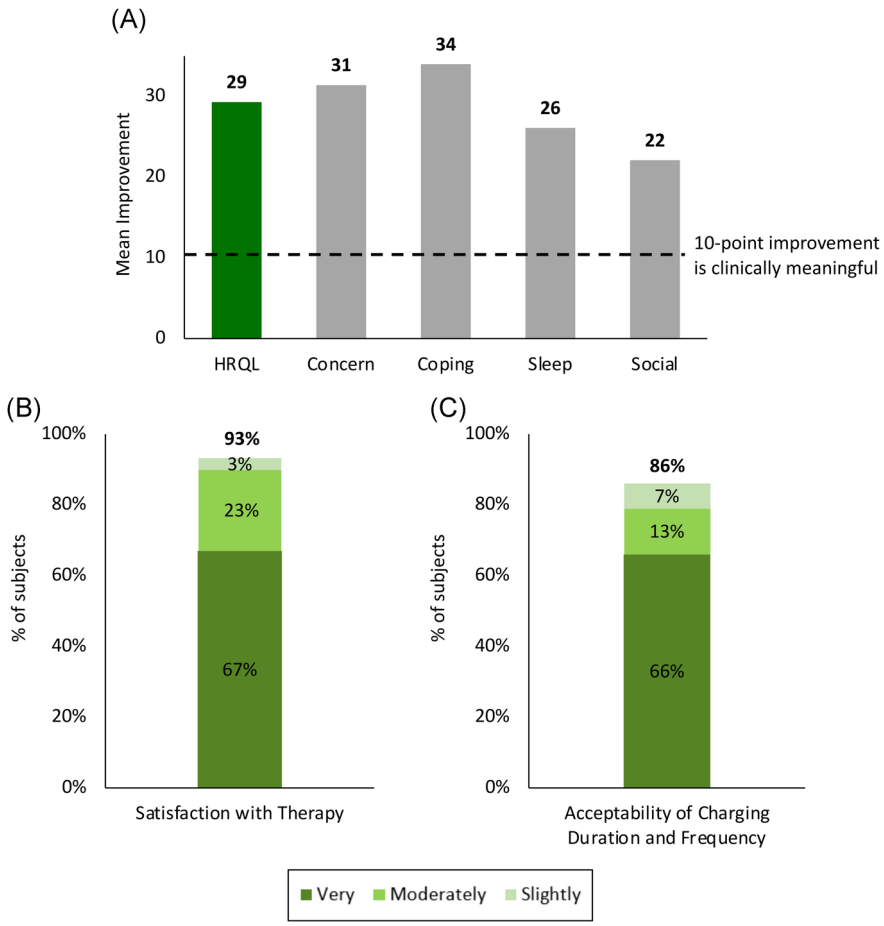

FIGURE 3 Quality of life, therapy satisfaction, and charging usability in Test Responders at 2 years. (A) Mean improvement in health-related quality-of-life (HRQL) composite score and all subscale scores show clinically and statistically significant improvements compared to baseline (*P<.0001 for all comparisons). All scores exceeded the minimally important difference of 10 points, which is considered clinically meaningful to patients for improvement in the quality of life.[4,12] (B) Satisfaction with their therapy. (C) Acceptability of charging duration and frequency

Of all implanted UI subjects available for follow-up, 76% (22/29) were therapy responders. Leaks per day reduced from 9.3 (±0.8) at baseline to 3.6 (±1.1), an average reduction of 5.8 (±0.9) ($P < .0001$).

Sixty-one percent (61%) of all implanted UF subjects available for follow-up (22/36) were therapy responders. Voids per day reduced to 8.6 (±0.8), an average reduction of 6.3 (±1.1) voids ($P < .0001$).

Of all implanted subjects available for follow-up, 87% (33/38) were satisfied with their therapy, and 86% reported that the duration and frequency of charging their system were acceptable.

Diary data were available for seven Test Failures, and satisfaction data were available for eight Test Failures (subjects that did not respond to SNM therapy in the first month). At 2 years, 14% of the Test Failures (1/7) were therapy responders. Sixty-three percent of the Test Failures (5/8) reported being satisfied with their rechargeable SNM therapy at 2 years.

3.2.3 | Safety

There were no unanticipated AEs or serious device-related AEs.

A total of 21 device-related AEs occurred in 13 subjects (26% of all subjects). A total of 8 of the 21 AEs (38%) occurred during the initial 2 weeks after implant. The most common device-related AE was undesirable or uncomfortable stimulation (13 events in 10 subjects, or 20% of subjects), which was resolved with reprogramming in all subjects. Pain at the neurostimulator implant site occurred in one subject (2% of all subjects) and was resolved with reprogramming. One incident of lead migration occurred between 3- and 6-months post-implant in a subject that engaged in high-intensity sports and heavy lifting. There was one event of suspected lead fracture as indicated by high impedances.

Of 51 implanted subjects, a total of 7 subjects (14%) have been explanted at 2 years, 5 (10%) of which are Test Failures. In Test Responders, the explant rate at 2 years is 6% (2/34 Test Responders). Of the seven explanted subjects, one subject was explanted at 3 weeks due to procedure-related infection at the neurostimulator incision site. Four subjects were explanted due to lack of efficacy, three of whom were initial Test Failures, and one who was an initial success but then lost efficacy. Of the remaining two subjects, one was explanted due to high impedances, and one due to the need for a magnetic resonance imaging (MRI) scan. The Axonics System is now approved in Europe, Canada, and Australia for full-body 1.5- and 3-T MRI scans under specific conditions. The Axonics System is also approved in the US for 1.5-T full-body scans and 3-T head MRI scans under certain conditions.

3.2.4 | Stimulation parameters and impedances

Average stimulation parameters are available for the 39 subjects that completed 2-year visits are shown in Table 1. Stimulation frequency was 14 Hz in 82% of subjects and pulse width was 210 μs in 90% of subjects. Subjects were primarily on bipolar electrode configurations (100% at 2 years) and no subjects had cycling activated.

Impedance values were recorded from implant to 2 years. Impedance increases by 35% from 2 weeks postimplant to 6 months and then by 3% from 6 months to 2 years (Figure 4).

4 | DISCUSSION

OAB is a chronic condition that has a significant impact on quality of life. Medications to treat OAB require daily dosing, and compliance rates at 1 year can be as low as 18%.[13] SNM has been shown to be a durable therapy with maintained efficacy out to 5 years,[6] indicating that patients responding to therapy initially are likely to continue to be long-term responders.[6,7] Axonics' long-lived rechargeable SNM device is ideal for providing long-term efficacy and satisfaction.

The results of the RELAX-OAB multicenter study are consistent and comparable with the current SNM literature and confirm the sustained long-term safety and

TABLE 1 Average stimulation parameters

Visit	n	Amplitude, mA Mean ± SD (min, max)	Frequency, Hz Mean ± SD (min, max)	Pulse width, μs Mean ± SD (min, max)
1 mo	50	1.6 ± 1.1 (0.50, 6.0)	13.9 ± 0.6 (10, 14)	208.8 ± 6.0 (180, 210)
3 mo	48	1.7 ± 1.1 (0.50, 5.5)	14.3 ± 1.6 (14, 24)	210.6 ± 11.6 (180, 270)
6 mo	48	1.8 ± 1.2 (0.55, 5.8)	15.4 ± 6.1 (14, 55)	210.6 ± 11.6 (180, 270)
1 y	45	1.8 ± 1.4 (0.55, 6.9)	14.8 ± 3.7 (10, 33)	208.0 ± 7.6 (180, 210)
2 y	39	1.9 ± 1.5 (0.4, 6.9)	14.5 ± 2.9 (10, 24)	204.6 ± 16.5 (150, 210)

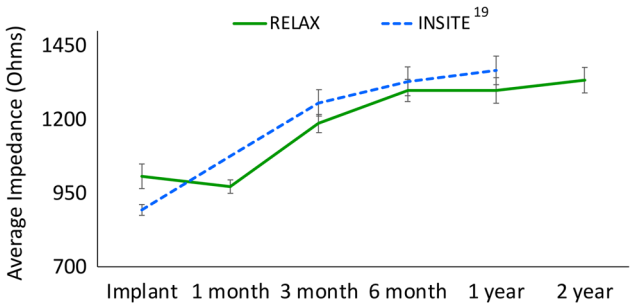

FIGURE 4 Average active electrode impedances of the Axonics System in all implanted subjects from device implant to 2 years postimplant (green line). Impedance data from the InSite are presented for comparison (dotted blue line)[19]

sustained efficacy of the Axonics System at 2 years. Another study investigating the Axonics System, ARTISAN-SNM, reported high responder rates (90%) at 6 months in 129 urinary urgency incontinence patients.[11]

The Axonics System is the first rechargeable SNM device to gain regulatory approval in the United States, Europe, Canada, and Australia. Initial satisfaction with the charging experience was reported as favorable by the majority of the study subjects in the RELAX-OAB study at 3 months and 1 year. At 2 years, the subject acceptance of the duration and frequency of charging remained high at 86%. A high rate of acceptance of charging the system was also reported in the ARTISAN-SNM study.[11] Given the chronic nature of this condition and the need for ongoing therapy, this data is reassuring and supports high patient satisfaction with the charging experience over the long term. These results are also consistent with rechargeable spinal cord and deep brain neurostimulators, where high rates of patient satisfaction with rechargeable neuromodulation systems are reported.[14,15]

One of the factors distinguishing the Axonics System from the incumbent device is that the Axonics device delivers constant current stimulation while the Medtronic InterStim device is voltage-controlled. Previous studies conducted in other neuromodulation systems, such as deep brain stimulation and spinal cord stimulation, have shown that constant current stimulation provides more consistent activation of the target nerve as compared to voltage-controlled systems and may allow for superior efficacy and higher patient preference.[16,17] Future studies designed to replicate these findings with SNM systems are needed.

The RELAX-OAB study differs from most other SNM clinical studies in that patients did not first undergo an external trial but instead received a full implant. This eliminated the need for subjects to "qualify" to receive the implant, reducing patient risk by avoiding a second surgery in all patients, and allowed for evaluation of all implanted subjects. Sixty-three percent of the Test Failures reported being satisfied with the treatment and one Test Failure (14%) became a therapy responder at 2 years. Assessing patient satisfaction captures the overall patient experience, and is an important consideration given the limitations of the responder rate definition which is based solely on a limited set of measures from voiding diary data.

There were no unanticipated device-related AEs and no serious device-related AEs reported out to 2 years. The majority of the device-related AEs were reported in the first year with only two AEs reported from 12 to 24 months. The most commonly reported AE was undesirable or uncomfortable stimulation, and all events were resolved with reprogramming. This was also the most commonly reported AE in the InSite Trial.[18] At 2 years, a total of two subjects (4%) were explanted for infection and high impedances. The low number of overall device-related AEs and device-related explants at 2 years is encouraging.

The long-lived rechargeable Axonics System has the potential to eliminate several surgical revisions needed for battery replacements, and a lower surgical revision rate is expected to reduce the occurrence of pain at the neurostimulator site. Additionally, given that the size of the Axonics neurostimulator is only 5 cc in volume (1/3 the volume of the Medtronic device), it was anticipated that there would be less pain at the neurostimulator site. Our data support this assumption, with only one subject (2%) in the RELAX-OAB study reporting pain at the neurostimulator site up to 2 years, which was resolved with reprogramming. Similarly, at 6-months in another study using this miniaturized implant, less than 2% of subjects reported pain at the neurostimulator site.[11] The low rate of implant site pain with the Axonics neurostimulator contrasts with the Insite study results, where 7% (20) of subjects experienced pain at the neurostimulator site at 1 year, 65% (13) of whom had to undergo surgical intervention with two having permanent explant. At 5 years, the rate of implant site pain in the Insite study was 15%.[6] This data suggests that the smaller long-lived Axonics neurostimulator results in less pain at the implant site and less need for surgical intervention.

5 | CONCLUSION

The RELAX-OAB multicenter study demonstrates that the Axonics System provides sustained clinically meaningful improvements in OAB subjects at 2 years. Subjects were satisfied with their therapy and reported that their recharging experience was acceptable. Additionally, no unanticipated device-related AEs were reported, and no serious device-related AEs occurred throughout this study.

The clinical results and safety profile of the RELAX-OAB study are consistent, if not superior, to the current clinical data on the use of SNM to treat OAB.

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