

ARTISAN-SNM Clinical Study Overview

Study Overview



PURPOSE

Pivotal multicenter study



SAMPLE

Urinary urgency incontinence (UUI)



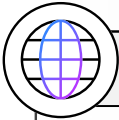
SIZE

n = 129
(single nonstaged procedure)



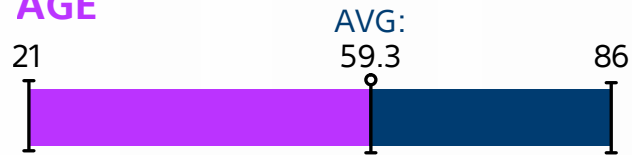
ENROLLMENT CRITERIA

1. Diagnosis of UUI demonstrated on a 72-hour voiding diary defined as:
 - ≥ 4 leaking episodes associated with urgency
 - $\geq 50\%$ of leaking episodes associated with urgency
 - ≥ 1 leaking episode per 24 hours
2. ≥ 6 months' history of UUI diagnosis
3. For male subjects only:
 - Peak flow rate > 15 cc/s (uroflowmetry ≤ 6 months prior enrollment)
 - Residual bladder volume < 150 cc (test ≤ 6 months prior enrollment)
4. ≥ 21 years of age
5. Willing and capable of providing informed consent
6. Capable of participating in all testing associated with this clinical investigation



PATIENT DEMOGRAPHICS

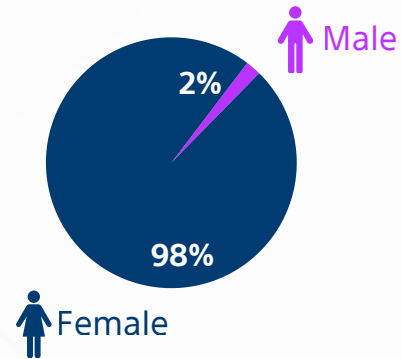
AGE



BMI*

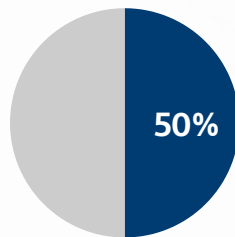


GENDER

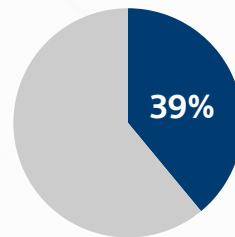


SECONDARY DIAGNOSIS

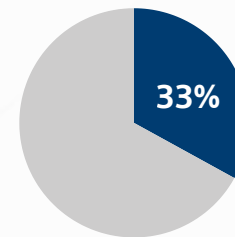
Urgency Frequency



Stress Incontinence

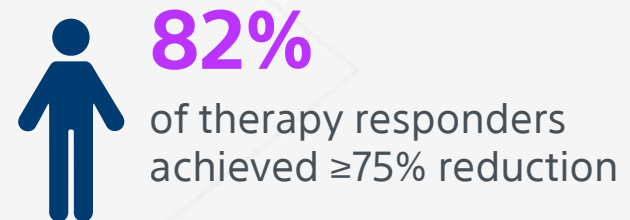
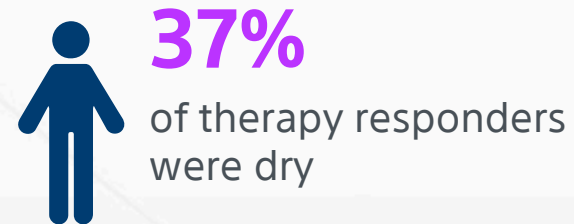
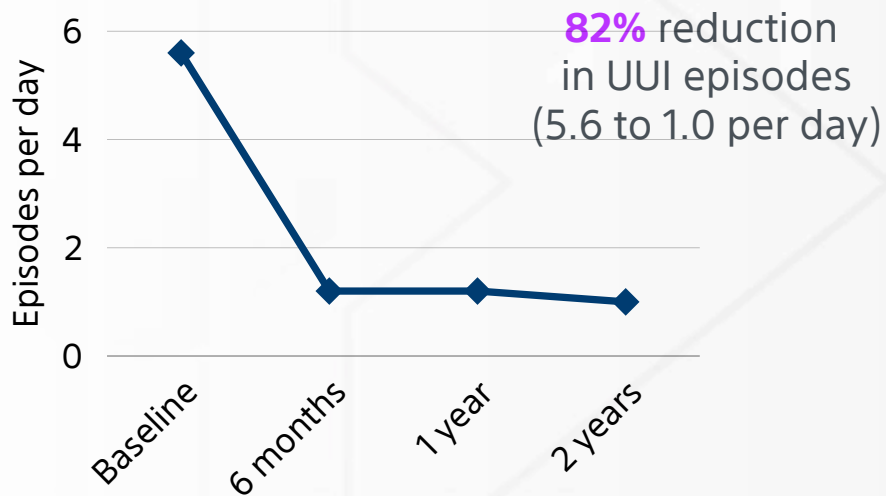
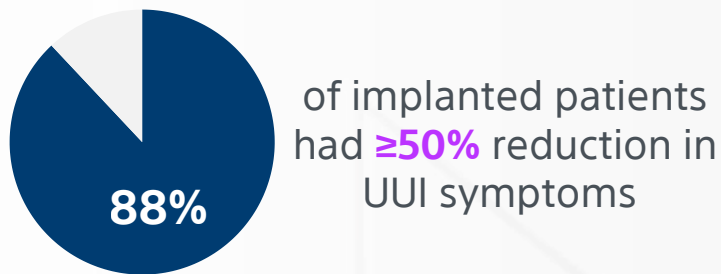


Fecal Incontinence



2-Year Outcomes

Significant Reductions in UUI Episodes

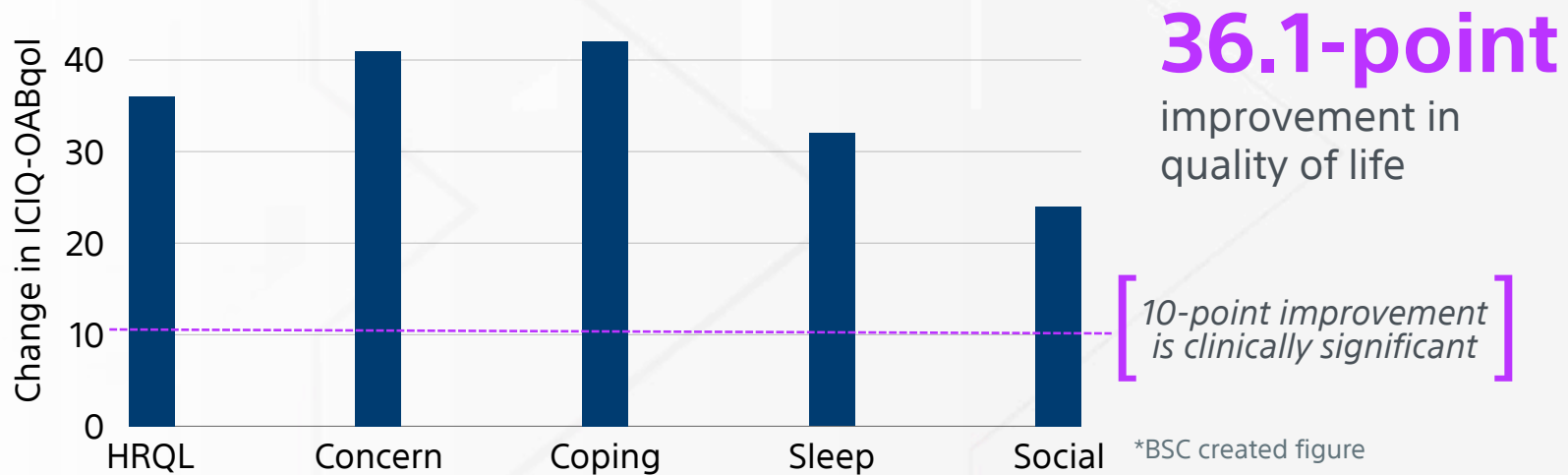


2-Year Outcomes

Safety Profile

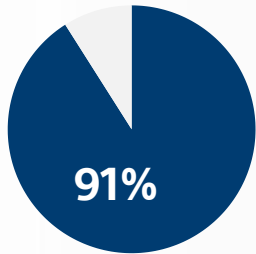
No unanticipated or serious device- or procedure-related adverse events were reported at 2 years

Clinically Meaningful Improvements in Quality of Life

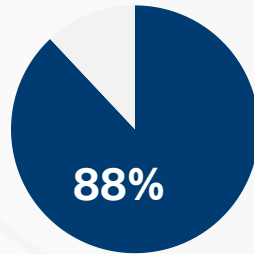


2-Year Outcomes

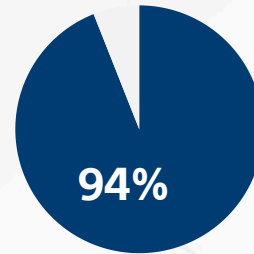
Rates of Patient Satisfaction



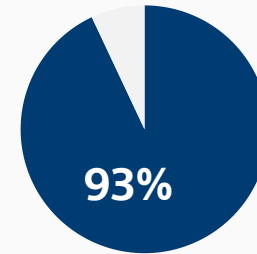
Recharging as
"easy"



Recharge in
<1 hour



"Satisfied"
with therapy



Would undergo
therapy again



“ This therapy makes me feel young again because now I can do anything. I have more freedom to come and go as I please. I am very satisfied with this system. ”

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

References

1. Pezzella A, McCrery R, Lane F et al. Two-year outcomes of the ARTISAN-SNM study for the treatment of urinary urgency incontinence using the Axonics rechargeable sacral neuromodulation system. *Neurourol Urodyn*. 2021;40(2):714–21
2. Benson K, McCrery R, Taylor C, et al. One-year outcomes of the ARTISAN-SNM study with the Axonics System for the treatment of urinary urgency incontinence. *Neurourology and Urodynamics*. 2020;1–7. <https://doi.org/10.1002/nau.24376>
3. McCrery R, Lane F, Benson K, et al. Treatment of urinary urgency incontinence using a rechargeable SNM system: 6-month results of the ARTISAN-SNM study. *The Journal of Urology*. 2020;203(1):185–192.
4. <https://clinicaltrials.gov/study/NCT03327948?term=artisan%20snm&rank=1#participation-criteria>

Important Safety Information

[Indications, Safety and Warnings for Axonics SNM System™](#)

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France. All trademarks are the property of their respective owners. All images are the property of Boston Scientific.

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