ARTISAN-SNM Clinical Study Overview

Study Overview

PURPOSE
US FDA pivotal study

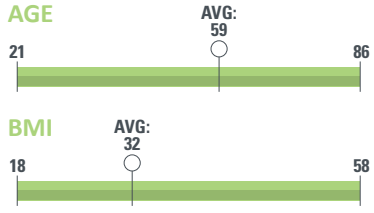
POPULATION
Urinary Urgency Incontinence (UUI)

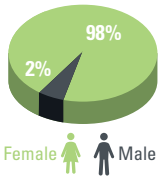
SIZE
129 patients implanted in a non-staged procedure

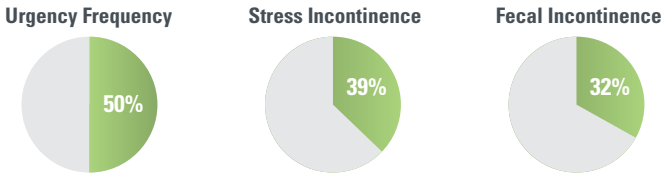
SITES
14 centers in the United States and 5 in Western Europe

ENROLLMENT CRITERIA
- Failed or could not tolerate first and second-line therapies
- UUI demonstrated on a 3-day voiding diary including at least 4 or more urgency leaks over 3 days
- Excluding moderate to high levels of stress incontinence or mixed incontinence

PATIENT DEMOGRAPHICS

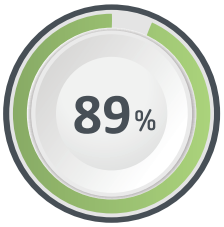




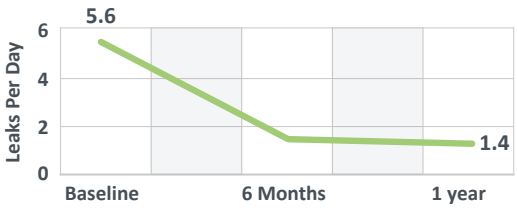


1-Year Outcomes

Significant Reductions in UUI Episodes



of implanted patients had ≥**50%** reduction in UUI symptoms



75% reduction in UUI episodes across all study patients

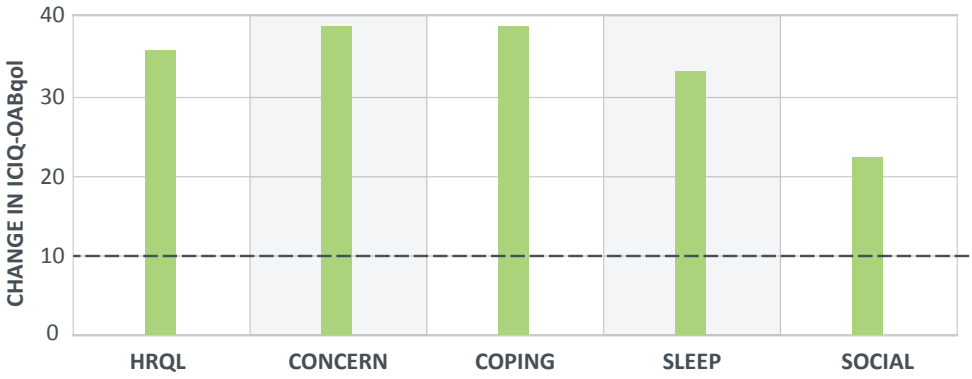
77%
of treatment responders had ≥**75%** reduction in urgency leaks

29%
of treatment responders were dry

Continued on back

Axonics

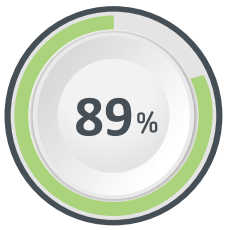
Clinically Meaningful Improvements in Quality of Life



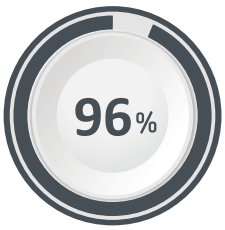
3X the criteria for clinically meaningful improvement

10-point improvement is clinically significant

High Rates of Patient Satisfaction

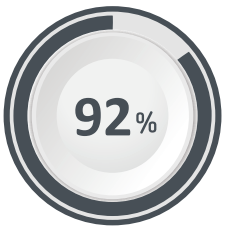


Charging is **"Easy"**



Charging frequency & duration is **"Acceptable"**

"Satisfied" with the therapy



Would undergo the therapy **again** with same expected results

"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."

Favorable Safety Profile

- Treatment with the Axonics System was well tolerated with no serious device-related adverse events reported.
- At 1 year,
  <2% of patients reported discomfort at the INS site, with no surgical revisions necessary
  <1% rate of lead migration was observed
  <1% rate of lead fracture was observed

For additional information on the ARTISAN-SNM clinical study (NCT03327948), go to clinicaltrials.gov