RESET STUDY OUTCOMES

Evidence from the RESET study on Percutaneous Tibial Neuromodulation (PTNM) delivered by the NURO™ system shows:

- NURO™ is an effective drug-free treatment for patients with overactive bladder (OAB), even if they have not previously tried OAB medication or are averse to medication.[1]
- The importance of finishing the therapy and waiting until sessions 8-12 to determine if a patient is or will respond to PTNM therapy.

PRESENTED AT SUFU 2019

~23%

of patients who eventually responded to NURO™ first responded at week 8 or later.*[2]

PRESENTED AT AUA 2018

~70%

reduction in UUI episodes per day at completion of 12 PTNM sessions.[1]

PRESENTED AT AUGS 2018

~90%

reduction in the proportion of patients who reported having severe or very severe problems with their overactive bladder (OAB) .[3†]

FINISH THE THERAPY FOR OPTIMAL RESULTS

Results showed a trend for continued improvement in symptom relief, quality of life, and patient reported outcomes as patients completed more NURO™ sessions, and they had the best results when finishing the 12-session therapy.[1-5]

Complying with the treatment for 12 sessions can improve the patient's quality of life and decrease OAB symptoms.[1-5]

Safety: There were no serious or unanticipated adverse device effects. The most common adverse events (AE) were medical device site pain (3.3%, 4/121) and extremity pain (3.3%, 4/121).

- Does your practice wait past session 6 to determine if your patient has responded to PTNM therapy?
- Do you have patients who are averse to medication for OAB?
- How might a drug-free approach to OAB help your patients?

Medtronic

PRESENTED AT ICS 2018

Greater Improvement

in HRQL than What is Considered "Clinically Significant"[4,5‡]

- Statistically significant improvement in total health-related quality of life (HRQL) and its subscales — including concern, coping, sleep and social — as well as symptom bother.[5‡]
- PTNM patients experience significant quality of life (QOL) improvements.[5]

RESET STUDY OVERVIEW

- Multicenter, single arm (all patients received NURO™ PTNM), prospective study sponsored by Medtronic
- Patients with OAB received 12 weekly PTNM sessions with the NURO™ system
- Study assessed voiding diaries, quality of life and other patient reported outcomes, and safety
- Analyses were based on patients who had data at baseline and follow-up visits

PATIENT PROFILES

- 120 patients, none of which had tried OAB medication prior to enrollment
- Mean Age: 64.8
- Mean duration of OAB diagnosis: 3.4 years
- Gender mix: 86% female

* Response defined as ≥50% improvement in UUI episodes/day vs baseline.
† Evaluated using the Patient Perception of Bladder Condition (PPBC) scale.
‡ Evaluated using the Overactive Bladder Symptom Quality of Life Questionnaire (OAB-q).

References

1. Kobashi K, Khandwala S, MacDiarmid S, et al. A Prospective Study to Evaluate Efficacy with the NURO Percutaneous Tibial Neuromodulation System in Drug Naïve Patients with overactive bladder syndrome (OAB). Presented at the American Urological Association 2018 Annual Meeting. Journal of Urology. 2018;199(4) Supplement, Page e987.
2. Kobashi K, Sand P, Margolis E, et al. Increasing therapy effect over twelve weeks with the NURO™ percutaneous tibial neuromodulation system in drug naïve patients with overactive bladder syndrome (OAB). Presented at the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction 2019 Winter Meeting.
3. Sand P, Kobashi K, Margolis E, et al. Patient Reported Outcomes with Percutaneous Tibial Neuromodulation (PTNM) therapy in Drug Naïve Patients with Overactive Bladder (OAB) Syndrome. Presented at the American Urogynecologic Society 2018 Annual Scientific Meeting.
4. Coyne KS, et al. 2006. Determining the importance of change in the OAB-q. *J Urol* 176:627-32.
5. Kobashi K, Margolis E, Sand P, et al. Prospective Study to Evaluate Quality of Life with Percutaneous Tibial Neuromodulation in Drug-Naïve Patients with Overactive Bladder Syndrome. Presented at the 2018 Annual Meeting of the International Continence Society.

Indication for Use:
Medtronic NURO™ Percutaneous Tibial Neuromodulation is intended to treat patients with overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.
Contraindications: Do not use on patients with pacemakers or implantable defibrillators, patients prone to excessive bleeding, patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function, or on patients who are pregnant or planning pregnancy.
Warnings/Precautions/Adverse Events: Do not use if the skin in the area of use is compromised. Exercise caution for patients with heart problems. There were no serious or unanticipated AEs. Adverse events are typically temporary, and include mild pain, minor inflammation and bleeding near treatment site. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at professional.medtronic.com/NURO. Product technical manual must be reviewed prior to use for detailed disclosure.
USA Rx only. Rev 0915

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