



Urgent[®] PC

THE PROVEN PTNS DEVICE



Innovation for Health

URGENT[®] PC NEUROMODULATION SYSTEM

Since 2003, Urgent PC has set the standard for Percutaneous Tibial Nerve Stimulation (PTNS) performance, both in clinical studies and in clinical practice. In fact, it is the strength of the Urgent PC data and advocates, which led to the inclusion of PTNS in guiding documents such as the AUA/SUFU Overactive Bladder (OAB) Guideline.

PROVEN CHOICE: FOR MOST OAB PATIENTS

Because Urgent PC is low-risk with few contraindications and no severe adverse events, it's a good option for most OAB patients. PTNS is a recommended therapy in the AUA/SUFU OAB guideline.¹

- Effective in both men and women, regardless of age²
- Low-risk – few contraindications, no severe adverse events
- May be combined with behavioral and drug therapies

URGENT PC CANDIDATES INCLUDE THOSE:

- Too old and/or frail for other therapies
- Suffering intolerable side-effects from other therapies
- Experiencing insufficient response to drugs
- Already receiving BOTOX[®] injections
- Unwilling to perform self-catheterization
- Needing future MRIs
- Who want a non-drug, non-surgical option



The tibial nerve can be easily accessed in the lower leg. During an office visit, stimulation travels from the point of entry near the ankle, up the tibial nerve and to the Sacral Plexus.



PROVEN VALUABLE: EXPANDS CLINICAL PRACTICE

Over the past decade, we have worked to optimize the use of PTNS, establishing national reimbursement and developing a proven methodology of incorporating Urgent PC into clinical practice.

- In a community practice, 77.5% of responders continued long-term therapy with a treatment every 1-3 months³
- Delivered by qualified support staff under physician supervision
- Treat more patients using group appointments and staggered start times
- CPT[®] code 64566: national Medicare reimbursement; numerous private payer coverage policies
- Wide range of support tools, co-developed with clinical practitioners

PROVEN EFFECTIVE: 50 STUDIES DEMONSTRATE PRODUCT PERFORMANCE

A robust data set demonstrates that PTNS with Urgent PC is effective with consistent results in 3 randomized control trials (RCTs), 3 durability studies, 2 meta-analyses and over 50 peer-reviewed articles.

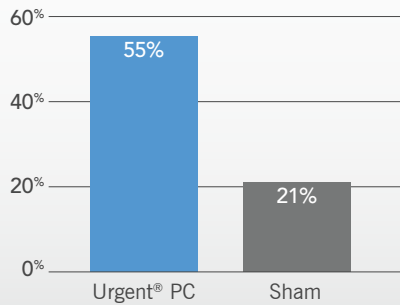
Statistically superior to sham in reducing frequency, incontinence episodes, nighttime voids and urgency⁴

Superior subjective response to leading OAB drugs with statistically significant reductions in OAB symptoms^{5,6}

At 3 years follow-up, all Quality of Life (QoL) parameters remained markedly improved with about 1 treatment a month (all $p < 0.0001$)⁶

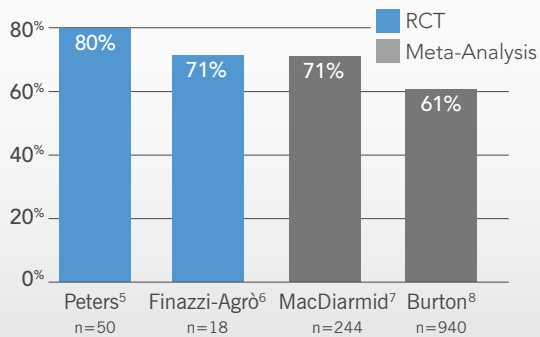
URGENT® PC SUPERIOR TO SHAM (P<0.001)

Patients Reporting Improvement at 12 Weeks⁴



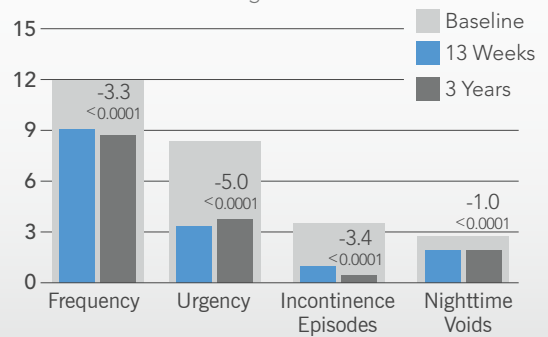
URGENT® PC OBJECTIVE SUCCESS

Results from RCTs and Meta-Analyses



URGENT® PC SUSTAINED EFFECTIVENESS⁷

Objective Improvement in Responders Attending 3 Year Visits



THE PROVEN PTNS DEVICE

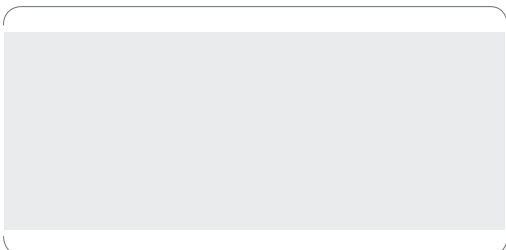
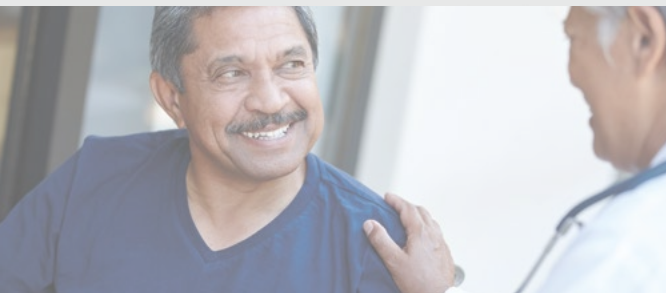
URGENT® PC NEUROMODULATION SYSTEM

- Option for most OAB patients
- Up to 80% patient response in men and women²⁻¹⁰
- More than a million treatments since 2003
- Easy to integrate into clinical practice
- System components sold separately and include an Urgent PC Stimulator and Urgent PC Lead Sets (box of 12)

CATALOG NUMBER	PRODUCT DESCRIPTION	PROCEDURE REQUIREMENTS
UPC 200	Reusable Urgent® PC Stimulator 1 Hand-held Stimulator, 1 9-Volt Battery, 1 Screwdriver, 1 Instructions for Use	1 unit
UPC 250-12	Urgent PC Lead Sets 12 Lead Sets/box, 1 9-Volt Battery, 1 Instructions for Use	1 lead set

1. Gormley, E.A, Lightner, D.J., Burgio, K.L., Chai, T.C. Clemens, J.Q, Culkins, D.J., et. al.(2014). Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline. Retrieved Sept. 8, 2014 from http://www.auanet.org/content/media/OAB_guideline.pdf
2. Peters, K., Carrico, D. (2013). Clinical insights into percutaneous tibial nerve stimulation (PTNS) versus sham therapy for the treatment of overactive bladder syndrome (OAB): secondary analysis of the SUMiT Trial. Poster presentation, SUFU winter meeting, Las Vegas, NV.
3. Leong, F.C., McLennan, M.T., Barr, S.A., & Steele, A.C. (2011). Posterior tibial nerve stimulation in patients who have failed anticholinergic therapy: efficacy and time to response. *Female Pelvic Med Reconstr Surg*, 17(2), 74-5.
4. Peters, K.M., Carrico, D.J., Perez-Marrero, R.A., Khan, A.U., Wooldridge, L.S., Davis, G.L., et al. (2010). Randomized trial of percutaneous tibial nerve stimulation versus sham efficacy in the treatment of overactive bladder syndrome: results from the SUMiT Trial. *J Urol*, 183, 1438-43.
5. Peters, K.M., Leong, F.C., Shobeiri, S.A., MacDiarmid, S.A., Rovner, E.S., Wooldridge, L.S., et al. (2009). A randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the Overactive Bladder Innovative Therapy trial. *J Urol*, 182, 1055-61.
6. Vecchioli-Scaldazza, C., Morosetti, C., Beouz, A., Giannubilo, W., Ferrara, V. (2013). Solifenacin succinate versus percutaneous tibial nerve stimulation in women with overactive bladder syndrome: results of a randomized controlled crossover study. *Gynecol Obstet Invest*, 75(4), 230-4.
7. Peters, K.M., Carrico, D.J., Wooldridge, L.S., Miller, C.J. & MacDiarmid, S.A. (2013). Percutaneous tibial nerve stimulation (PTNS) for the long-term treatment of overactive bladder: three-year results of the STEP Study. *J Urol*, 189(6), 2194-2201.
8. Finazzi-Agrò, E., Petta, F., Sciobica, F., Pasqualetti, P., Musco, S., & Bove, P. (2010). Percutaneous tibial nerve stimulation effects on detrusor overactivity incontinence are not due to a placebo effect: a randomized, double-blind, placebo controlled trial. *J Urol*, 184, 2001-06.
9. MacDiarmid, S.A., & Staskin, D.R. (2009). Percutaneous tibial nerve stimulation (PTNS): a literature-based assessment. *Curr Blid Dysf Rept*, 4, 29-33.
10. Burton, C., Sajja, A., & Latthe, P.M. (2012). Effectiveness of percutaneous posterior tibial nerve stimulation for overactive bladder: a systemic review and meta-analysis. *NeuroUrol Urodyn*, 31(8), 1206-16.

CONTRAINDICATIONS: Treatment with Urgent PC is contraindicated for 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 patients who are pregnant or planning to become pregnant during the duration of the treatment. **PRECAUTION:** Exercise caution for patients with heart problems related to pacing. Most patients do not experience side-effects. If side-effects occur, they are typically temporary and include mild pain and skin inflammation at or near the stimulation site. **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions and disclaimer of warranties, please refer to the insert accompanying each Urgent PC product. Urgent, BOTOX and CPT are registered trademarks. Urgent PC is manufactured by Uroplasty, LLC. Models are for illustrative purpose only. ©2018 LABORIE. All rights reserved.



USA:
5420 Feltl Road
Minnetonka, MN 55343

Tel.: 866 258 2182
Fax: 866 255 4522



www.laborie.com