

Urgent[®] PC

NEUROMODULATION SYSTEM

· 10 YEARS ·

The Proven
PTNS Device

· 50 STUDIES ·



The Proven PTNS Device

- » Percutaneous Tibial Nerve Stimulation (PTNS)
- » Option for most overactive bladder patients
- » Up to 80% patient response in men and women¹⁻⁹
- » More than a million treatments since 2003
- » Easy to integrate into clinical practice

Cogentix
Medical

Urgent[®] PC

NEUROMODULATION SYSTEM

The Proven PTNS Device

Since 2003, Urgent PC has set the standard for 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 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.¹⁰

- » Effective in both men and women, regardless of age¹
- » Low-risk – few contraindications, no severe adverse events
- » May be combined with behavioral and drug therapies

Urgent PC candidates include those:

- » Too old/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



Tibial nerve is easily accessed in the lower leg. During 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, Cogentix Medical has worked to optimize the use of PTNS, establishing national reimbursement and developing a proven methodology of incorporating Urgent PC into clinical practice.

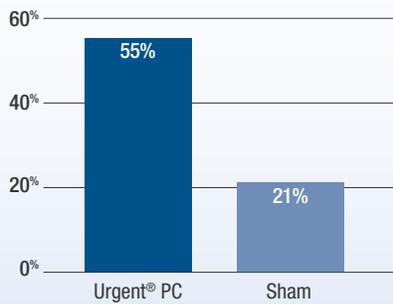
- » In a community practice, 77.5% of responders continued long-term therapy with a treatment every 1-3 months²
- » Delivered by qualified support staff under physician supervision
- » Treat more patients using group appointments and staggered start times
- » CPT[®] code 64566: national Medicare reimbursement; numerous private payer coverage policies
- » Wide range of support tools, co-developed with clinical practitioners

Proven Effective: 50 studies over 10 years

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

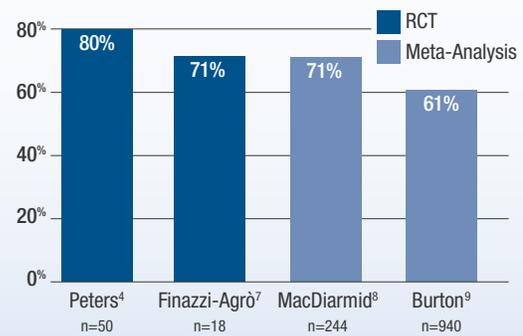
Urgent® PC Superior to Sham (p<0.001)

Patients Reporting Improvement at 12 Weeks³



Urgent® PC Objective Success

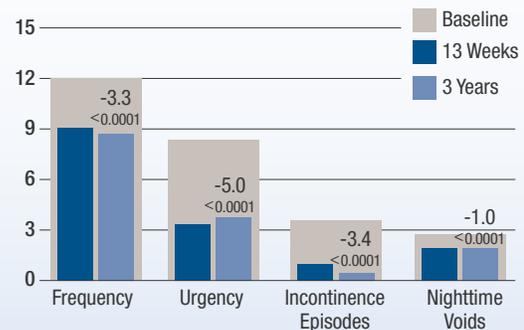
Results from RCTs and Meta-Analyses



- » Statistically superior to sham in reducing frequency, incontinence episodes, nighttime voids and urgency³
- » Superior subjective response to leading OAB drugs with statistically significant reductions in OAB symptoms^{4,5}
- » At 3 years follow-up, all QoL parameters remained markedly improved with about 1 treatment a month (all p<0.0001)⁶

Urgent® PC Sustained Effectiveness⁶

Objective Improvement in Responders Attending 3 Year Visits



Urgent[®] PC

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Product Information

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

- 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.
- 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.
- 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.
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- 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.
- 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.
- 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.
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- 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.
- 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

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 or online at www.cogentixmedical.com. Urgent, BOTOX and CPT are registered trademark. Models are for illustrative purpose only. ©2015 Cogentix Medical. All rights reserved. 20158E 08/15

Connect with Cogentix Medical



Cogentix
Medical

Cogentix Medical
5420 Feltt Road
Minnetonka, MN 55343

cogentixmedical.com

TEL 866.258.2182
FAX 866.255.4522