

## Medtronic Launches Percutaneous Tibial Neuromodulation Delivered by the NURO System for the Treatment of Overactive Bladder (OAB)

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*New Medtronic Treatment Targets Underlying Bladder and Brain Miscommunication and Could Bring Desperately Needed Relief to Tens of Millions Struggling with OAB*

**DUBLIN - March 30, 2016** - Medtronic plc (NYSE: MDT) today announced the launch of its NURO(TM) System that delivers percutaneous tibial neuromodulation (PTNM) for the treatment of overactive bladder (OAB) with symptoms of urinary urgency, urinary frequency, and urge incontinence. PTNM, a minimally invasive, periodic, office-based procedure, provides a measurable reduction in urinary frequency and/or urinary incontinence episodes following treatment without the side effects of medication.<sup>1,2</sup>

The number of OAB patients is staggering and increasing - more than 37 million Americans, or nearly 1 in 6 suffer - it is more common than diabetes or asthma.<sup>3,4,5,6</sup> While not life threatening, OAB significantly impacts quality of life, and can negatively affect social activities, exercise and cause disruptive nighttime voiding.<sup>7,8</sup> Many sufferers are frustrated and embarrassed and limit their lives socially, professionally, and personally.<sup>9</sup> However, only 33 percent of those suffering seek treatment and as many as 7 in 10 stop using medications within 6 months due to intolerable side effects or unsatisfying results.<sup>10,11</sup>

"Many people with OAB are unsatisfied with current treatments and a significant number are not seeking treatment altogether," said Dr. Harriette Scarpero, of Associated Urologists of Nashville, Tennessee. "With the NURO System, I can offer patients another option to restore bladder function and improve quality of life without the side effects of medication. This minimally invasive therapy targets the brain-bladder miscommunication and can help improve quality of life in a meaningful way."

The NURO System delivers a gentle electrical pulse to the tibial nerve via an acupuncture-like needle placed in the skin near the ankle that is attached to a neurostimulator. The therapy is administered in physician offices during weekly 30-minute sessions for 12 weeks and thereafter as prescribed by a physician. Patients are free to read or listen to music while therapy is administered. The most common side effects are temporary and include mild pain or skin inflammation at or near the stimulation site.

Evidence points to OAB being caused by a miscommunication between the bladder and brain.<sup>12</sup> Medtronic Bladder Control Therapies use neuromodulation, or gentle nerve stimulation, to reset the brain-bladder communication pathway. PTNM is thought to improve bladder function by targeting the tibial nerve, indirectly activating the central nervous system to help alleviate symptoms.

In clinical trials PTNM significantly decreased the number of incontinence episodes and voids per day, reduced the number of urgency and urge incontinence episodes and increased voiding volume.<sup>1,14</sup> With maintenance therapy, PTNM can offer long-term relief.<sup>15</sup>

"So many suffer from OAB and the majority are either not treated or not finding relief with other treatments, so Medtronic is pleased to offer another option along the care pathway," said Linnea Burman, vice president and general manager, gastro/urology therapies at Medtronic. "Our hope is that our expanding neuromodulation portfolio can help a broader range of patients get their lives back."

Medtronic offers NURO patients the Support Link® program that provides education, helps patients track their treatment and encourages compliance throughout therapy.

## Multimedia Release

A multimedia version of this release, with animation and an image can be found at: <https://medtronicmediacap.gcs-web.com/medtronic-launches-percutaneous-tibial-neuromodulation-delivered-nuro-system-treatment>.

### **About Medtronic Bladder and Bowel Control Therapies**

Medtronic is the first and leading provider of neuromodulation solutions for bladder and bowel control issues. With a portfolio that spans OAB, non-obstructive urinary retention and fecal incontinence, we partner with healthcare providers to offer advanced and comprehensive pelvic floor neuromodulation solutions to help more patients find the right therapy option. Sacral neuromodulation therapy with the InterStim® system was first approved in 1997 and has helped more than 200,000 patients worldwide.

### **About Medtronic**

Medtronic plc ([www.medtronic.com](http://www.medtronic.com)), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in more than 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

**Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.**

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#### References:

1. Van Balken, M. R., V. Vandoninck, et al. (2001). "Posterior tibial nerve stimulation as neuromodulative treatment of lower urinary tract dysfunction." *J Urol* 166(3): 914-918.
2. Peters, K. M., S. A. Macdiarmid, et al. (2009). "Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial." *J Urol* 182(3): 1055-1061.
3. Stewart WF, J.B. Van Rooyen, et al. (2003). "Prevalence and burden of overactive bladder in the United States." *World J Urol* 20(6): 327-336.
4. United Nations, Department of Economic and Social Affairs, Population Division (2011). *World Population Prospects: The 2010 Revision, CD-ROM Edition*.
5. Adult self-reported lifetime asthma prevalence rate (percent) and prevalence (number) by state or territory: BRFSS 2010. Centers for Disease Control and Prevention website. <http://www.cdc.gov/asthma/brfss/2010/lifetime/tableL1.htm>. Updated August 27, 2012. Accessed January 25, 2016.
6. National diabetes statistics report, 2014. National Diabetes Information Clearinghouse website. <http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>. Updated 2014. Accessed January 25, 2016.
7. Coyne, K. S., C. Payne, et al. (2004). "The impact of urinary urgency and frequency on health-related quality of life in overactive bladder: results from a national community survey." *Value Health* 7(4): 455-463.
8. Cartwright, R., S. Srikrishna, et al. (2011). "Validity and reliability of patient selected goals as an outcome measure in overactive bladder." *Int Urogynecol J* 22(7): 841-847.
9. Dmochowski RR, Newman DK. Impact of overactive bladder on women in the United States: results of a national survey. *Current Medical Research and Opinion*. 2007;23:65-76.
10. Muller, N. (2005). "What Americans understand and how they are affected by bladder control problems: highlights of recent nationwide consumer research." *Urol Nurs* 25(2): 109-115.
11. Yu YF, Nichol MB, Yu AP, et al. Persistence and adherence of medications for chronic overactive bladder/urinary incontinence in the California Medicaid Program. *Value in Health*. 2005;8(4)495-505.
12. Leng WW, Morrisroe SN. Sacral nerve stimulation for the overactive bladder. *Urol Clin N Am*. 2006;33:491-501.
13. Govier, F. E., S. Litwiller, et al. (2001). "Percutaneous afferent neuromodulation for the refractory overactive

bladder: results of a multicenter study." J Urol 165(4): 1193-1198.

14. Peters, K.M., D.J. Carrico, 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(4):1438-1443.
15. Peters, K.M., D.J. Carrico, et al. (2013). "Percutaneous tibial nerve stimulation for the long-term treatment of overactive bladder: 3-year results of the STEP study." J Urol 189(6): 2194-2201.

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