

CYSTOMEDIX'S URGENT® PC NEUROMODULATOR

For Treatment of Overactive Bladder

An estimated 12 million Americans have some problem with an overactive bladder (OAB). OAB is abnormal at any age and is a highly prevalent condition that affects both genders, but is more common in women. OAB has a combination of symptoms including urgency (the strong need to urinate), frequency (repetitive need to void), and/or urge incontinence (the unwanted urine leakage that happens shortly after urgency). OAB is of sufficient severity to require treatment in 16% of the U.S. population, with costs to the healthcare system exceeding \$25.6 billion. The OAB market is growing every year, largely due to the graying of the population.

Instead of seeking help, many people with OAB adjust their habits and lifestyle to accommodate the management of symptoms. The good news, however, is that OAB is treatable. **Cysto-Medix** (Minneapolis, MN) offers a minimally invasive, patient-friendly solution to the vexing problem of OAB. The **Urgent® PC Neuromodulator** modulates bladder function through electrical stimulation of the afferent nerve fibers of the tibial nerve bundle in the lower leg. The stimulatory pulses are delivered in a well-defined regimen and are thought to "reset" micturition sensitivity within the brain while also improving the compliancy of the bladder. Few treatment options are known to have both central and peripheral mechanisms of action. The fundamental advantage of the Urgent PC Neuromodulator is that it works to adjust the body's natural nervous impulses to improve homeostasis. It is a treatment option that can help patients gain control over this condition and improve the quality of their lives. Toby Chai, MD, Associate Professor of Urology at the University of Maryland and Urologist at the University of Maryland Hospital (Baltimore, MD),

prescribes the Urgent PC Neuromodulator for patients who have OAB with urge incontinence. "It's a good option to use before more aggressive therapies are contemplated. We have a very high percentage of patients who respond to this form of treatment. Patients who have received treatment with the Urgent PC are very pleased with the benefits."

The Urgent PC Neuromodulator consists of a small 34-G needle electrode, surface electrode, lead wire, and handheld electrical generator. The percutaneous needle is inserted into the ankle. After the lead wire and electrode are attached, the Urgent PC Neuromodulator is turned on and amplitude is slowly increased until the patient's large toe starts to curl, the toe digits fan out, or the entire foot extends, indicating proximity to the nerve bundle. The Urgent PC Neuromodulator produces an adjustable electrical pulse that travels up to the sacral nerve plexus via the tibial nerve. Amplitude is then reduced slightly and treatment is continued for 30 minutes. The patient is treated once per week for 30 minutes. Significant reductions in urge frequency and intensity have been reported after approxi-



mately 12 weeks of treatment. In addition, there have been reports of significant reduction in pain when the Urgent PC Neuromodulator was used for pain management. Treatment frequency may be slowly reduced while the patient is closely observed for the return of symptoms. If symptoms reappear or increase in severity, patients can return to the last previously effective treatment schedule.

Fah Che Leong, MD, Assistant Professor, Department of Obstetrics, Gynecology and Women's Health Division of Urogynecology, Saint Louis University School of Medicine (St. Louis, MO), has been prescribing this form of treatment for his patients since 1998. The major-

ity of Dr. Leong's patients who use the Urgent PC Neuromodulator have not been able to control their condition with other forms of treatment, such as medication, behavioral therapy, or even surgery. "My patients say that the best thing about treatment with the Urgent PC is that they feel *normal* and they no longer have symptoms of OAB. I had a patient whose condition was so severe that she needed to wear adult diapers day and night. Now, after treatment with the Urgent PC, she no longer needs to wear any protection. Once patients have completed the initial treatment regimen, we are able to reduce them to treatments only once every 3 months. An additional benefit is that the treatment has no side effects and is just about painless."

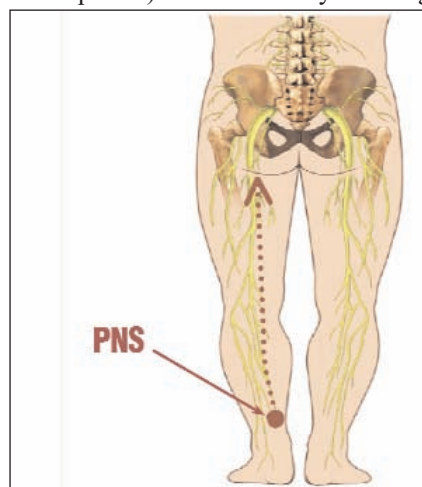
Neuromodulation vs. Neurostimulation

The efficacy of the Urgent PC Neuromodulator is about the same as is reported with sacral nerve stimulation (SNS) therapies, but it is significantly less invasive and less costly. Treatment with the Urgent PC Neuromodulator is simple to begin and simple to end because there are no implanted components as in SNS therapies. SNS therapy involves the use of a surgically implanted medical device that sends constant mild electrical pulses to targeted areas of the nervous system. Treatment with the Urgent PC Neuromodulator, on the other hand, is in short, periodic intervals. This treatment system uses a disposable percutaneous needle electrode and the stimulation is applied via peripheral nerves. The Urgent PC Neuromodulator works with the body's naturally emitted signals and fine-tunes them, exerting

long-lasting and powerful reductions in OAB symptoms.

How does the Urgent PC Neuromodulator compare to drug treatments?

Drug therapy is a common option for most patients. However, there are not as many effective pharmaceutical choices specifically for treating OAB, and those currently available on the market usually have side effects that may be bothersome (e.g., dry mouth, constipation). The efficacy of drug



treatments is not high, and it has been reported that only about 50% of the patients respond to that form of therapy. Furthermore, many patients with OAB have mixed symptoms that cannot be addressed by a single therapy and are in need of additional treatment. These patients may benefit from drug therapy used in conjunction with the Urgent PC Neuromodulator.

Pathophysiology of OAB

The causes of OAB include any factor causing an aberration in the complex interplay between the muscles of the

bladder, internal and external sphincters, and the nerves and neurotransmitters that control them, as well as the complex neural circuitry between the bladder, spinal cord, brain stem, and the higher brain centers or cerebrum. While these changes often are due to diseases or traumas that affect the nervous system, they also can occur due to childbirth or simply due to aging. The prevalence of OAB has been poorly understood. In the past, many experts believed that such voiding dysfunction symptoms as urgency and frequency were harmless and did not cause significant problems for individuals. New research shows that the triad of symptoms—urinary frequency, urgency, and urge incontinence, alone or in combination, can have a significant impact on someone's quality of life

Market Availability

The Urgent PC Neuromodulator is approved by the FDA and EU community for market distribution and has several U.S. and O.U.S. patents. The Urgent PC also is reimbursed by all the insurers.



For more information concerning Urgent PC Neuromodulator or CystoMedix, Inc., contact Paul Sandstrom at 1-763-427-6509; e-mail to psandstrom@cystomedix.com; contact a CystoMedix representative at AUA, booth #4416; or visit the company Web site at www.cystomedix.com.