

Media Contact: Sandra Van
Telephone: 1-800-880-2397
E-mail: sandy@prpacific.com

HIGHLIGHTS:

According to the American Urogynecologic Society, 13 million Americans experience incontinence and 11 million of them are women. When traditional treatments aren't effective, some patients with severe urge incontinence are experiencing good results with an implantable "bladder pacemaker" that generates electrical pulses to decrease the number of bladder contractions. This, in turn, reduces the symptoms of urgency and frequency associated with urge incontinence.

BLADDER PACEMAKER TREATMENT RELIES ON ELECTRICAL PULSES TO REDUCE SYMPTOMS OF URGE INCONTINENCY

LOS ANGELES (May 22, 2005) – As Wendy Simmons goes about her job as a sales clerk in a women's clothing store, it's not uncommon for strangers to approach her and ask, "Are you the lady with the bladder pacemaker?"

While some women might shy away from this type of notoriety, Simmons is comfortable sharing the details of her struggle with urinary urge incontinence and how her life's changed for the better since having a relatively unknown treatment called InterStim therapy at Cedars-Sinai Medical Center. "I love helping people," she says, "and I want to be a part of making this treatment better known."

According to the American Urogynecologic Society, incontinence affects approximately 13 million people in the United States, – 11 million of whom are women. Urge incontinence is one of several types of incontinence, and is characterized by the sudden loss of urine at the wrong time and the wrong place. With urge incontinence, or "overactive bladder," the bladder contracts in an uncontrolled way even when it's not full. People of all ages can experience urge incontinence, depending on what the underlying problem is.

Gary Leach, M.D., a highly renowned urologist and co-director of the Women's Center for Continence and Pelvic Health at Cedars-Sinai, is one of only a few physicians in the United States actively using the bladder pacemaker (InterStim device) for patients with severe urge incontinence. While the U.S. Food and Drug Administration approved the therapy in 1999, Leach believes most doctors and patients are not aware of it.

As he explains, when treating women with severe bladder problems, there are three different indicators for using the bladder pacemaker device. The most common is refractory overactive bladder – a bladder that is unresponsive to treatment. Women with this condition have severe frequency and urgency incontinence and none of the usual medications have worked for them. The second indication is urinary retention (inability to urinate) and the third is pelvic pain. Some patients with interstitial cystitis who experience pelvic pain as their bladder fills have found the pacemaker therapy very helpful, he says.

"The good thing about this procedure is that it's done in two stages," says Leach. "In the first phase, we do a test to see if the device will work for this particular patient. This is an outpatient procedure and the patient is under local anesthesia for 20 to 30 minutes, and then goes home from the hospital the same day. Usually within seven to 10 days we have a very good idea as to whether they will respond to treatment (an estimated

(more)

70 to 80 percent respond positively), and if they do, we go ahead with the second phase.”

During the first phase, Leach inserts a thin wire electrode next to one of the sacral nerves in the back that controls the bladder. This wire (which sends a signal to the nerve to tell the bladder to relax) is attached to a battery pack (about the size of a pager) that the patient wears on her belt for a week to 10 days. The battery pack generates electrical pulses which decrease the number of bladder contractions, thereby reducing the symptoms of urgency and frequency. For the next week or so the patient keeps a record of how often she urinates and how many sanitary pads she wears each day.

If the patient returns and reports that she is significantly improved, says Leach, then he proceeds to the second phase during which he implants a small pulse generator that looks like a cardiac pacemaker in the patient’s upper buttocks area and attaches it to the wire that is already in place. This second phase is also an outpatient procedure under local anesthesia and is completed within 15 minutes.

“The beauty of this procedure is that we can test it to see if it works. If the patient comes back after the first phase and says she’s only about 10 percent better, then we don’t do the second phase. Instead, other options are pursued. For example, if the pacemaker procedure does not work for a patient, another procedure called augmentation cystoplasty, can be performed in which the bladder can be enlarged to three or four times its normal size by using a segment of the small intestine. While it is often successful in curing incontinence, many patients find that they are unable to empty their bladder well after this procedure and need to self-catheterize three to four times each day.

Leach reports that approximately 70 to 90 percent of his patients have a good response to the first phase of the Interstim trial and go on to have the pacemaker implanted. Once implanted, the device can be reprogrammed with a computer through the skin so it’s not unusual, he says, for a patient to return to his office to have the device adjusted until the right setting is found.

Simmons says that her co-workers are “shocked by the difference the surgery has made in me. It’s amazing. I used to be in and out of the bathroom all the time. Before this surgery I basically lived my life worrying about going to the bathroom. Now, for the first time in many years, I don’t have any infections, I don’t leak urine and I don’t have to self-catheterize. I can sleep through the night without getting up to go to the bathroom. I just go about my business, going to the movies and out to dinner ... incontinence isn’t an issue for me anymore.”

For more information about Cedars-Sinai’s Women’s Center for Continence and Pelvic Health, call (310) 423-9558. One of only five hospitals in California whose nurses have been honored with the prestigious Magnet designation, Cedars-Sinai Medical Center is one of the largest nonprofit academic medical centers in the Western United States. For 17 consecutive years, it has been named Los Angeles’ most preferred hospital for all health needs in an independent survey of area residents. Cedars-Sinai is internationally renowned for its diagnostic and treatment capabilities and its broad spectrum of programs and services, as well as breakthroughs in biomedical research and superlative medical education. It ranks among the top 10 non-university hospitals in the nation for its research activities and was recently fully accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). Additional information is available at www.cedars-sinai.edu.

###

If you have received this news release in error and do not wish to receive future advisories, or if they should be directed to someone else in your organization, please call 1-800-396-1002, so we can update our records. Alternatively, you may fax your updated information or your request for removal from our list to 808-263-3364 or e-mail it to sandy@prpacific.com.