SOUTHWESTERN NEWS

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NEW FDA-APPROVED DEVICE TO TREAT INCONTINENCE AVAILABLE AT UT SOUTHWESTERN

DALLAS – November 18, 1997 – People who are severely incontinent now have access to a new Food and Drug Administration-approved implant available in Texas only at UT Southwestern Medical Center at Dallas.

The Sacral Nerve Stimulation System is for people for whom conventional methods have been ineffective or inconsistent in controlling urine discharge. The device is similar to implanted heart pacemakers. It has a small wire hooked to a small stimulator surgically implanted in a pocket under the skin. The frequency and amount of stimulation can be programmed with a hand-held remote control.

"This will be of great benefit to patients who are debilitated by their incontinence," said Dr. Scott Litwiller, an assistant professor of urology. He recently trained in the Netherlands on using the stimulator, which has been approved for use in Europe since 1994. The device has been tested in 10 medical centers in the United States since 1993, but the FDA just approved it for general clinical use. UT Southwestern is one of the few places in the country where patients will have access to the treatment.

"People who are good candidates for this treatment are those whose lives essentially are governed by their symptoms. Every time they leave their offices or their houses, they have to know where the next restroom is," Litwiller said. "They can't go to movies or restaurants. They hate to even leave the house."

Before being considered for implantation of the nerve stimulator, a patient must meet certain criteria: failure of treatments such as dietary change, medications and biofeedback to correct their conditions; normally functioning kidneys and ureters; bladders that can hold a normal amount of urine; otherwise generally healthy; and positive results of response to sacral

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nerve stimulation.

The test is a peripheral nerve evaluation (PNE), in which a patient is monitored for three or four days with a temporary device. If the response to the stimulation seems good, and incontinence symptoms return several weeks after PNE is over, the patient may be a candidate for the permanent implant.

In clinical trials, as many as 61 percent of the tested patients experienced a 90 percent improvement in symptoms. The amount of improvement depended on the individual; it can take up to six months to see marked lessening of symptoms.

The manufacturer of the Sacral Nerve Stimulation System, Medtronic Interstim, also recently received FDA approval for an apparatus that uses almost identical technology to treat some tremors.

Litwiller, of the UT Southwestern Clinical Center for Bladder and Incontinence Treatment, and Dr. Andrea Holliday, assistant professor of neurological surgery, are both seeing patients interested in treatment with the implant.

Further information can be obtained by calling the UT Southwestern Urology Clinic at (214) 648-3070.

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