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THE RENESSA[™] SYSTEM: A NEW, NON-SURGICAL SOLUTION FOR FEMALE STRESS URINARY INCONTINENCE

Novasys Medical, Inc. (Newark, CA), dedicated to the development of innovative therapies in women's health, has recently launched its first product: the **Renessa[™] System**, a novel, non-surgical approach to treat female stress urinary incontinence (SUI) due to bladder outlet hypermobility. The Renessa procedure, a catheter-based treatment that uses radio frequency (RF) energy to increase bladder outlet resistance, now offers women and their physicians a unique treatment for SUI that can be performed in a physician's office, and has a rapid and comfortable recovery and minimal post-procedure limitations. The Renessa treatment has an excellent safety profile and has been shown to be well tolerated with high patient satisfaction.

The Renessa procedure applies controlled heat at low temperatures in tissue targets within the lower urinary tract, denaturing collagen at multiple small treatment sites. Upon healing, these treated sites reduce tissue compliance without luminal narrowing or stricture, and increase resistance to involuntary leakage at times of increased intra-abdominal pressure, thereby reducing or eliminating SUI episodes. The microscopic alterations in submucosal collagen do not change luminal caliber and are associated with a safety profile comparable with that of a brief bladder catheterization. A physician performs the procedure in-office in approximately 20 minutes using a single-use transurethral probe. No visualization of the treatment site is required. The procedure can be performed using local anesthesia with oral sedation. The

procedure requires no incisions, bandages, or dressings, and women can safely resume most activities within 24 hours.

In a U.S. clinical trial, 76 percent of women who underwent the Renessa procedure experienced a reduction in daily incontinence episodes at 12 months following treatment; 68 percent of women used fewer pads each day; 58 percent of women no longer used incontinence pads each day; and 35 percent of women were continent (cured).



With currently available surgical and non-surgical SUI therapies, many patients and physicians have concerns about safety, recovery, compliance, and effectiveness. In fact, it is estimated that approximately 80 percent of women with SUI do not seek treatment of any kind due to these concerns. Behavioral and biofeedback therapies for SUI are plagued by limited success and patient compliance issues. Some surgical treatments have demonstrated acceptable success,

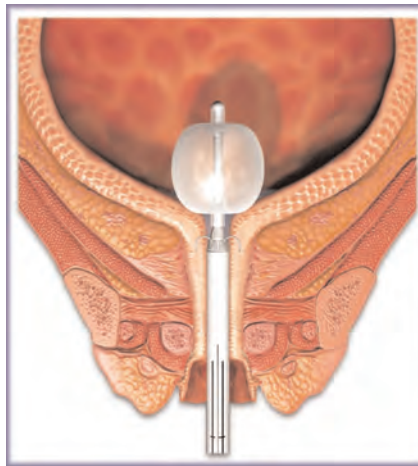
but are associated with high costs, perioperative morbidity, patient discomfort, and the need for pelvic rest. The Renessa System, on the other hand, represents an approach that could be considered one of the least invasive, yet most effective treatments available. Urologist John G. Christensen, Jr. MD, FACS (Wheaton, IL), says that the Renessa treatment is "a completely unique, brand new way of treating SUI." What Dr. Christensen likes about the Renessa treatment is that "it is an office-based procedure, it is simple to perform, it is very well tolerated, and there are essentially no

risks to the patient. So far we have treated three patients, and all of them are now dry.”

What attracted Denise Elser, MD, Illinois Urogynecology, Ltd. (Oaklawn, IL), to the Renessa treatment was that it “presented a great option for some ladies who are not surgical candidates, such as the older patients who may be afraid of surgery because they have other medical problems and maybe ought not to have anesthesia or surgery, or the very young patients who started having kids at a young age or have bad tissue and have incontinence that’s unbearable. I’m not causing tissue destruction or putting in a device that’s going to block future treatments for this young patient.” About two-thirds of Dr. Elser’s patients are coming back with great results, and tell her “they have little or no pain and they would definitely recommend the Renessa treatment to a friend.”

Rodney A. Appell, MD, Department of Urology, Baylor College of Medicine (Houston, TX), had this to say about the Renessa treatment: “There are no medications currently available for this disorder, and any other treatment, beyond behavioral modification and bio-feedback is surgical, which makes the Renessa treatment quite unique. This procedure has the positive aspects of being able to be performed in 20 minutes under local anesthesia in a doctor’s office, with a markedly significant improve-

ment rate that has durability for at least one year.” As for convenience and recovery, Dr. Appell notes, “Patients can get up and leave at the end of the procedure. There are no catheters and no bleeding—just a follow-up office visit for a checkup. As for pain, the whole thing is done under local anesthesia and patients do not need to be sent home with any medication.” Dr. Appell finds that his patients are responding quite well to the treatment. “The short-term information we have on cure rate is about 40 percent and the improvement rate is about 80 percent, so it just depends on whether someone wants to go for complete dryness or whether they are satisfied with improvement rates.”




Urologist Angelo Kanellos, MD (Reno, NV), said that since receiving FDA approval, he has treated four SUI patients using the Renessa system and has had much success. “These four patients were treated with local anesthetic only as opposed to sedation given in the

outpatient surgical center. I was impressed that even done under local, tolerability was excellent and the majority of patients improved with regard to their stress incontinence.”

About Stress Urinary Incontinence

SUI is the most common type of urinary incontinence, affecting as many as 15 million women in the United States. The primary cause of SUI cases is inadequate support of the bladder, resulting in bladder outlet hypermobility. SUI affects women of all ages, including approximately 25 percent of women age 30-59 years, particularly those who have delivered at least one baby vaginally. Regardless of age group, stress urinary incontinence may have a dramatic negative impact on quality of life and can severely restrict social activity.

About Novasys Medical, Inc.

Novasys Medical, Inc. is a privately held, venture-backed company that develops innovative therapies in women’s health. The company’s initial focus is the development and commercialization of the Renessa System, a proprietary, non-surgical approach to the treatment of female stress urinary incontinence. 

For more information concerning Novasys Medical Inc., call 1-866-784-4777, or visit the company’s Web site at www.novasysmedical.com.