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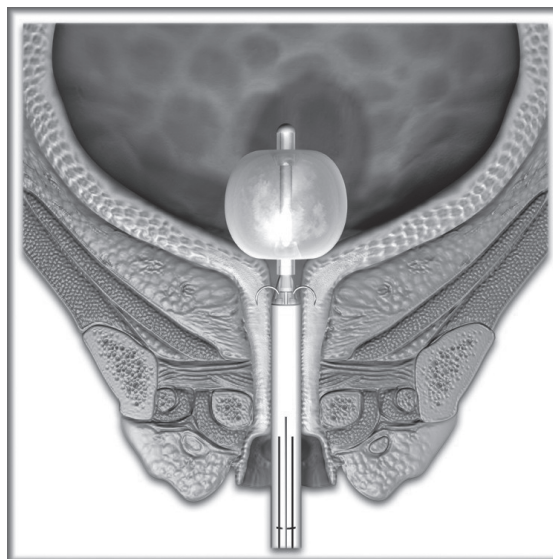
Renessa[®]

Unique Non-Surgical, In-Office Treatment Provides Option for Women with SUI

The FDA-cleared **Renessa[®] System** was recently launched into the marketplace and to date more than 1,000 women with Stress Urinary Incontinence (SUI) have been treated clinically. Developed by **Novasys Medical, Inc.** (Newark, California), a company dedicated to the development of innovative therapies in women's health, the Renessa procedure is a proprietary, non-surgical approach to treat female SUI due to bladder outlet hypermobility and represents an approach that could be considered one of the least invasive, yet most effective, treatments available. Long-term clinical outcomes have shown durable responses to the Renessa procedure and confirmed an improvement in quality of life with a reduction in the frequency and severity of incontinence episodes in the majority of women almost four years after treatment.¹

The Renessa System includes a small probe which a physician passes through the urethra. The probe heats multiple small treatment sites in the submucosa of the bladder neck and proximal urethra, denaturing collagen in the tissue. Upon healing, the treated tissue is less compliant, resulting in increased resistance to involuntary leakage at times of increased intra-abdominal pressure, such as laughing, coughing, or during exercise, thereby reducing or eliminating leaks. The Renessa procedure can be performed in the physician's office using local anesthesia. There are no incisions, bandages or dressings required. Recovery is rapid and comfortable, with minimal post-procedure limitations.

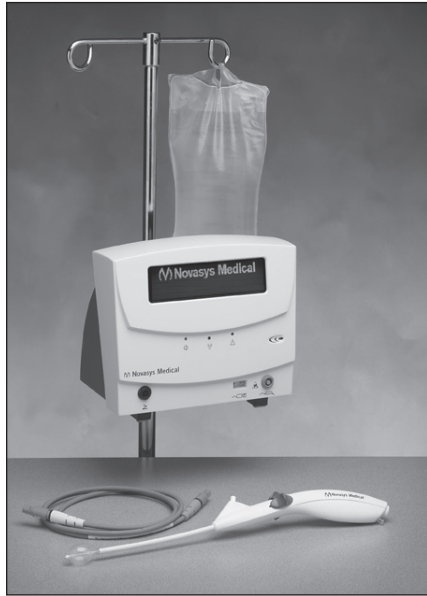
Nancy A. Little, MD, Lodi Memorial Hospital (Lodi, CA), recommends Renessa for women who have stress incontinence and no significant prolapse. Dr. Little has treated about 40 patients and reports that approximately 75 percent were improved. "I think that's a great percentage for a conservative treatment. My patients are very happy with the procedure—



it's simple and straightforward. The patients are in the office for about an hour, but the procedure itself takes only about 20-30 minutes. We use a periurethral block, so there is no pain involved and when it's done, the patients can just get up and walk out." Dr. Little feels strongly that women should have more options for treatment of SUI and says that "Renessa is the best option that has come along in a long time."

Treatment for SUI depends on the severity of the symptoms and the extent to which the symptoms interfere with an individual's lifestyle. There are currently no drugs approved by the FDA to treat SUI and patients often find limited or no success with traditional non-invasive methods, such as behavioral therapy or biofeedback. Certain patients have the option of treatment with an injection of bulking agents and for some there is the option of surgery. Rodney A. Appell, MD, Professor of Urology at Baylor College of Medicine (Houston, TX), explains that "for those patients who don't want or can't have a surgical procedure, but want something that will have a good chance of significantly improving their symptoms, Renessa gives patients an alternative,

especially when you can't guarantee the results of surgery. The longer term results for surgery show that 60 to 70 percent remain dry, which means there are still a significant



number of patients who do not.” When Dr. Appell offers the Renessa procedure as a treatment option to appropriate candidates, “they jump at it. The patients who have success from it are extremely satisfied and are glad that they didn’t have to undergo a surgical procedure.”


Physicians using the Renessa procedure report that their patient outcomes in the commercial setting are very consistent with those reported in the clinical trials. Saad Juma, MD, of the Incontinence Research Institute (Encinitas, CA), recently presented the results of a study on the long-term safety and effectiveness of the Renessa procedure at the Global Congress of Minimally Invasive Gynecology sponsored by the AAGL. Dr. Juma reported that long-term durability outcomes “sustained themselves after more than three years, which is a very

good sign.” This retrospective analysis evaluated the clinical results of women from a randomized controlled multicenter U.S. clinical trial that took place in 2002. Seventy-six percent of women experienced a reduction in daily incontinence episodes and nearly half of these women were completely dry; 58% of women no longer used incontinence pads; 67% of women reported an improvement in their quality of life; and 56% of women had a greater than 50% reduction in episodes. Satisfaction with the treatment and willingness to refer friends to the procedure remained high.²

Many urologists have the mistaken impression that women with SUI will only consider a treatment that has a high probability of making them completely dry when, in fact, most women are looking for an improvement in symptoms. Dr. Appell notes that “what physicians think and what patients want do not appear to be in sync. Studies have demonstrated that patients are willing to give up a little bit of dryness for fewer complications and less risk.” One such study set out to determine what women perceive as a “cure” and to assess the acceptability of treatment. The study revealed that 43 percent of women expected a good improvement of their symptoms so they no longer interfered with daily life versus only 17 percent who expected a complete cure of all symptoms. Furthermore, nearly two out of three women reported they would likely be satisfied with occasional small leaks on coughing, sneezing or strenuous exercise.³ Dr. Little agrees with these findings. “Surgical procedures to treat SUI are an option for individuals who want the best possible outcome and who are not concerned about restriction of activities.

These days, many women are too busy to take time off for surgery. They want something that can give them improvement, but don’t feel that they necessarily have to be cured of their leakage.”

Dr. Juma notes that “incontinence is a quality of life issue and curing it is not a realistic goal for a significant percentage of patients. That being the case, we ask how we can get the patient the most satisfaction for the minimum amount of effort. With Renessa, we can get 75 percent of patients to experience a reduction in incontinence episodes, which is very good, considering it’s such a minimally invasive procedure.”

SUI often restricts the social, professional, and personal lives of an estimated 15 million women in the U.S. alone. It is estimated that approximately 80 percent of women with SUI do not seek treatment of any kind due to concerns over recovery time, possible complications, or lack of confidence in the effectiveness of available options. 

To learn more about how the Renessa treatment may benefit your patients, call toll free 1-866-784-4777, e-mail info@novasysmedical.com, or visit the company’s Web site at www.novasysmedical.com.

References:

- 1,2. Appell, R, Juma, S, et al., Long-term Durability of a Non-surgical Transurethral Radiofrequency Treatment for Female Stress Urinary Incontinence: A Retrospective Analysis. Presented at the Global Congress of Minimally Invasive Gynecology, AAGL 35th Annual Meeting, November 2006.
3. Robinson D, et al. Department of Urogynaecology, Kings College Hospital. What women want—Their interpretation of the concept of cure.