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## Renessa®

### *In-Office, Non-Surgical Treatment for Women With Stress Urinary Incontinence ~ It's What Women Want ~*

**S**tress Urinary Incontinence (SUI) can have a major impact on a woman's quality of life, often restricting the social, personal and professional lives of nearly 30% of all women over the age of 18 in the United States. One study revealed that more than half of the women with SUI symptoms need to make changes in their lifestyle to avoid situations in which their condition might cause them discomfort or embarrassment, a trend that increases with age.<sup>1</sup>

One of the latest approaches to treating SUI is **Renessa®**, a proprietary, non-surgical approach to treat female SUI due to bladder outlet hypermobility. Developed by **Novasys Medical, Inc. (Newark, California)**, a company dedicated to the development of innovative therapies in women's health, the FDA-cleared Renessa treatment represents an approach that could be considered one of the least invasive, yet most effective treatments available. To date, nearly 3000 women with SUI have been treated clinically with Renessa. The procedure can be performed in a physician's office under local anesthesia.<sup>2</sup> 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.

Renessa has been shown to be very safe with no significant adverse events reported to date. In two large US clinical trials, women continued to experience improvement in SUI symptoms 12 months after treatment with Renessa. These



*Renessa probe positioned within the urethra and bladder.*

studies showed that 76% of women experienced a reduction in the number of leaks.<sup>3</sup> Nearly 60% were able to eliminate the use of pads and more than 70% of women reported an improvement in quality of life.<sup>4,5</sup> 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.<sup>6</sup>

Nancy A. Little, MD, of the Lodi Urological Medical Group (Lodi, CA), is a urologist who specializes in female incontinence. Dr. Little finds that Renessa fills an enormous void in the treatment of SUI. "I've been in practice here for 16 years. We have some very conservative options available for women with SUI, and then we have surgery. Until Renessa, we haven't been able to offer patients anything in-between." Dr. Little explains that people are busy--they want a treatment that is effective, but does not require a lot of down time. "While physical therapy and biofeedback can work for some women, it requires about six hours a week. With

a surgical procedure, patients can't do any heavy lifting or strenuous activity for six weeks after surgery. The Renessa procedure, on the other hand, takes approximately 45 minutes in the office, recovery is rapid and comfortable, and there are minimal post-procedure limitations."

Dr. Little makes two important points when it comes to treating SUI symptoms: (1) most women do not want to invest a lot of time in it, and (2) they are looking for improvement, not perfection. In fact, one recent study set out to determine what women perceive as a 'cure' and to assess the acceptability of treatment options. The study revealed that 43% of women expected a good improvement of their symptoms so they no longer interfered with daily life, versus only 17% 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.<sup>7</sup> This study also revealed that more than half of the women would be willing to accept some improvement (versus a full cure), if it meant they could undergo a less invasive procedure with a lower risk of complications.<sup>7</sup> Dr. Little finds this to hold true in her practice. "Most patients are looking for a 50% to 75% improvement, not complete dryness, and most women would be very pleased if they could go from wearing two or three regular pads a day down to wearing just a panty liner." Dr. Little notes that there are certain people who say that they want to be as dry as possible and that those patients are better candidates for surgery.

Ramon A. Perez, MD, of Urology Specialists of West Florida (Trinity, FL), says that when he discusses treatment options with his patients,



*Renessa probe with balloon inflated.*

anything that is minimally invasive attracts the attention of his patient population. "I find that many of my patients are very happy to sacrifice a little bit of perceived efficacy [when compared to a surgical procedure] for the fact that they can have a procedure done in the office, on their own schedule, without the fuss that a hospital-based procedure entails and without the cost attached to it. That makes Renessa a very appealing option for many of our patients." Dr. Perez has been actively using Renessa in the clinical setting for about eight months. "Our results have been remarkable. I would say that more than 90% have an improvement and more than 85% of the patients have significant improvement to the point where they don't need to use any protection." Dr. Perez notes that patients start seeing improvement at about eight weeks and that optimal improvement happens at about three months. "People always want to have the magic pill to cure everything. Luckily, my patients with SUI are very realistic about their expectations. The longer they have had the problem, the more realistic they are."

Dr. Perez has found that Renessa has also been a practice-building experience for him. "Renessa is a high-

profile therapy. We started marketing it about six months ago with a newspaper article. It is amazing how much interest and buzz it created in the community. We've also been to community-based organizations to introduce Renessa, and invariably there are three to five patients who come to see us as potential Renessa patients." ♦

To learn more about how the Renessa treatment may benefit your patients, call toll free 1-866-784-4777, e-mail [Renessa@novasysmedical.com](mailto:Renessa@novasysmedical.com), or visit the company's website at [www.novasysmedical.com](http://www.novasysmedical.com).

### References:

1. Muller N. What Americans understand and how they are affected by bladder control problems: highlights of recent nationwide consumer research. *Urol Nurs* 2005;25(2):109-115.
2. Vincent Lucente, MD, MBA Presentations from the 34th Clinical Meeting of the AAGL *Advancing Minimally Invasive Gynecology Worldwide* held November 2005 in Chicago, IL, USA. Can be accessed at <http://www.obgyn.net/aagl/2006/presentations/novasys.asp>.
3. Appell RA, Juma S, Wells WG, et al. Transurethral radiofrequency energy collagen micro-remodeling for the treatment of female stress urinary incontinence. *Neurourol Urodyn.* 2006;25(4):331-336.
4. Appell RA, Singh G, Klimberg IW, et al. Nonsurgical radiofrequency collagen denaturation for stress urinary incontinence: retrospective 3-year evaluation. *Expert Rev Med Devices.* 2007;4(4):455-461.
5. Sotomayor M, Barnal GF. Twelve-month results of nonsurgical radiofrequency energy micro-remodeling for stress incontinence. *Int Urogynecol J Pelvic Floor Dysfunct.* 2005;16(3):192-196.
6. 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.
7. Robinson D, et al. Department of Urogynaecology, Kings College Hospital. What women want – Their interpretation of the concept of cure. Abstract presented at IUGA 2002 and ICS 2002 Annual Meetings.