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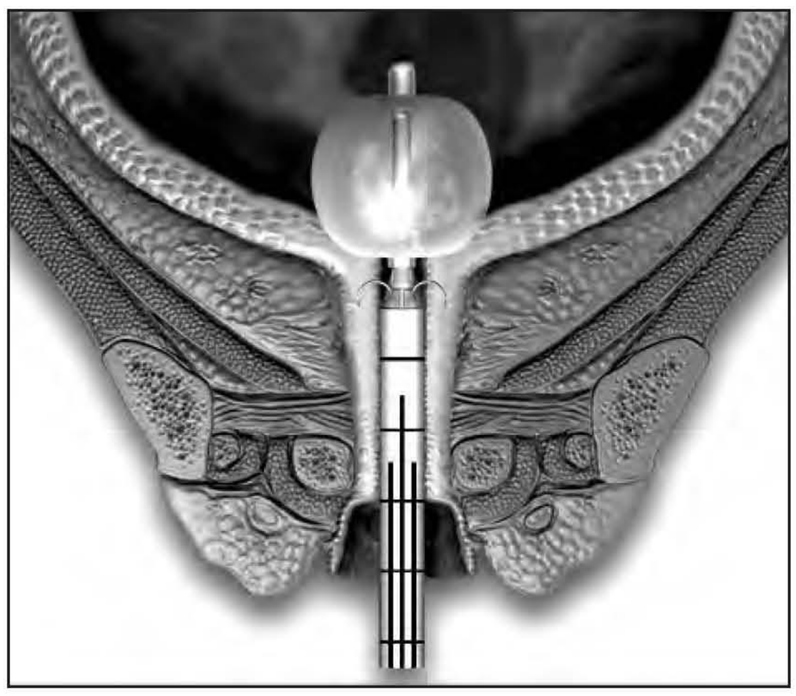
THE RENESSA® SYSTEM

An In-Office, Non-Surgical Option for Female Stress Urinary Incontinence

Stress urinary incontinence (SUI) is the most common type of urinary incontinence, affecting 15 million women in the United States alone. SUI affects women of all ages. Approximately 25% of women between 30 and 59 years of age who have delivered at least one baby vaginally are affected. Research indicates that SUI can be improved in most cases with the use of rehabilitation, behavioral therapies or a surgical procedure; however, estimates show that less than half of women affected by SUI ever seek medical treatment.[1] SUI can have a negative impact on a woman's quality of life, often restricting her professional, social and personal activities, while reducing her self-esteem as well.[2] One study revealed that almost 60% of women with SUI symptoms had 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.[3] Arnold J. Willis, MD, a urologist with Mid Atlantic Urology Associates (Washington, DC), is surprised by how many women have significant incontinence—either overactive bladder or stress incontinence—but choose not to discuss it with anyone, noting "few women get the attention or treatment they need to manage their condition." Estimates reveal that approximately 50% of women with SUI do not discuss their symptoms with physicians, and of those who do speak to their physician, only about 20% seek treatment of any kind.[4,5,6]

For those who seek treatment, the ultimate choice depends on the severity of the symptoms and extent to which the symptoms interfere with an individual's lifestyle. Some women opt for a surgical approach to treat their SUI. Surgery, however, comes with its own inherent risks and is followed by a recovery period.[7,8,9,10,11] A newer non-surgical procedure involves the use of low energy radiofrequency (RF) to remodel collagen in the submucosal tissue of the bladder neck and proximal urethra. The FDA-cleared **Renessa® System** from **Novasys Medical, Inc. (Newark, CA)**, is a proprietary technology used to treat SUI due to bladder outlet hypermobility that utilizes RF energy to generate controlled heat at low temperatures in tissue targets within the bladder neck and proximal urethra. The heat denatures collagen in the tissue at multiple small treatment sites. Upon healing, the treated tissue is firmer, increasing resistance to involuntary leakage at times of heightened intra-abdominal pressure, such as laughing, coughing or during exercise, thereby reducing or eliminating SUI episodes. The Renessa procedure can be performed in the physician's office using local anesthesia and there are no incisions, bandages or dressings required. Recovery is rapid and comfortable, with minimal post-procedure limitations. Renessa represents an approach that could be considered one of the least invasive, yet most effective, treatments

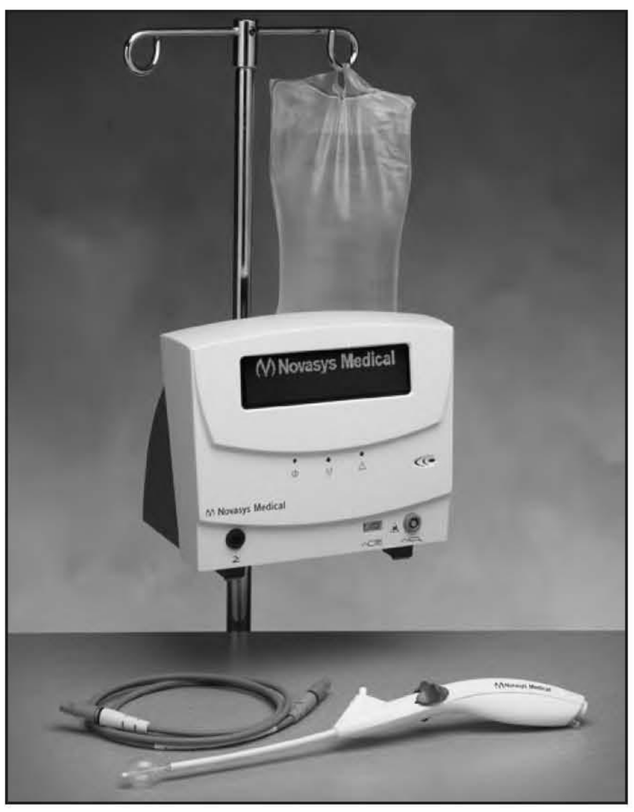


Renessa probe positioned within the urethra and bladder.

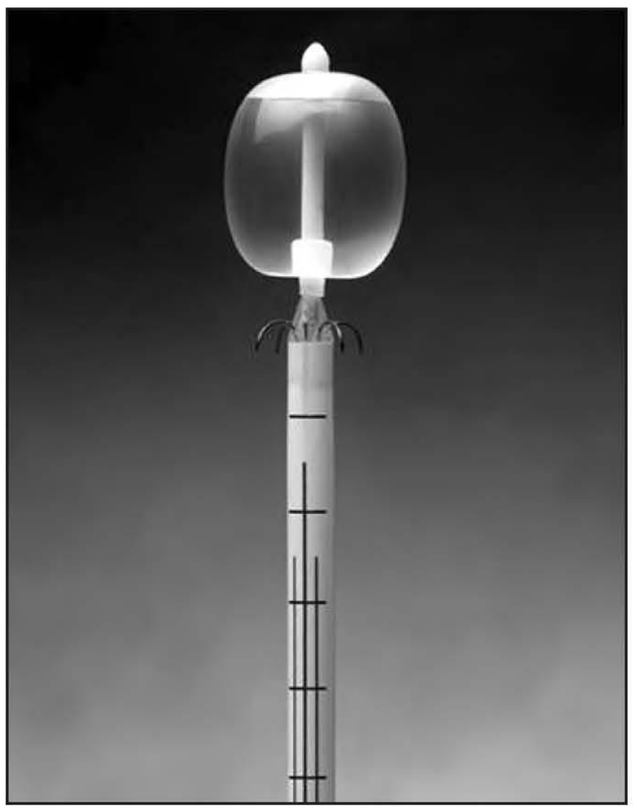
> *"This is an office-based procedure, using a local anesthetic. The risks are minimal and the results can be significant. When the procedure is finished, the patients can go home and the majority see results in a short period of time. I don't think you can ask for anything much better than that."*
>
> **Arnold J. Willis, MD** – Mid Atlantic Urology Associates, Washington, DC

available. To date, more than 2500 women with SUI have been treated clinically with Renessa. 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.[12] The safety of the Renessa treatment has also been well-established. There have been no reports of serious adverse events, and side effects have been mild and transitory.[2, 13, 14]

"If people understood the simplicity of Renessa, I think more women would opt to treat their SUI," notes Dr. Willis. One of the issues Dr. Willis encounters with his patients is that they are an active group of people. "Most women don't have time to go through surgery. They have obligations and can't afford the downtime that often follows surgical procedures or they might be concerned about surgery and the inherent risks involved. The bottom line is they want something that is less invasive, but also durable. This is where Renessa fits in beautifully." Dr. Willis continues, "This is an office-based procedure, using a local anesthetic. The risks are minimal and the results can be significant. When the procedure is finished, the patients can go home and the majority see results in a short period of time. I don't think you can ask for anything much better than that." Dr. Willis has been using Renessa regularly for about two and a half years and finds that of his patients who are good candidates for Renessa, eight out of ten opt to have the procedure. "My results have been excellent. About 50% of patients find they are completely dry and 70-75% see significant improvement." Dr. Willis closes by saying, "I love this procedure. I've been practicing



The Renessa® System



Renessa probe with balloon inflated.

for 30 years and have seen the progression from abdominal or retropubic surgeries with seven to ten-day hospital stays and bed rest to something that we can now do in the office. *This* is progress."

Results from a continuing 36-month trial have revealed thus far that non-surgical transurethral collagen denaturation for the treatment of women with SUI caused by bladder outlet hypermobility has resulted in significant, durable reductions in activity-related leak and improvements in quality of life.[2] Results at 12 months showed that 69% of women measured at least a 50% reduction in leaked volume on in-office stress pad weight test. The median reduction in volume was 8.3 grams from a baseline median volume of 9.9 grams. Twenty-nine percent of women were dry and an additional 16% of women leaked less than one gram. Fifty percent of the women had at least a 50% reduction in incontinence episode frequency. Further, 50% of patients reported "a little," "much," or "very much" better from baseline and 64% would recommend the procedure to a friend. The results at 18 months revealed much the same success as those from those measured at 12 months: 63% of patients had a 50% leak reduction. Seventy-one percent (up from 50% at 12 months) reported being "a little," "much," or "very much" improved. Overall, 61% of patients were "somewhat" or "very satisfied." This study continues to demonstrate the procedure is safe and no serious adverse events have been reported to date in this or any other trial, or in the commercial setting.[2]

Patients who benefit most from the Renessa treatment are those who: (1) leak at least twice a day, requiring the use of pads; (2) have bladder outlet hypermobility; (3) have Valsalva leak point pressures of at least 90cm H_2O demonstrated via urodynamics; and (4) have no history of overactive bladder or urge incontinence requiring treatment. Durwood E. Neal, Jr., MD, Professor and Chairman, Division of Urology, University of Missouri (Columbia, Missouri), feels that with Renessa, like most other medical procedures, patient selection is critical. "A bone-anchored pubovaginal sling will probably will work for just about everybody, but it has a higher risk profile than Renessa does. [With Renessa,] my patients have seen a moderate to complete improvement in urinary incontinence for mild to moderate symptoms and that is a situation that's pretty well borne out with all of the studies that have been done." Dr. Neal further notes that for physicians, not only is it a straightforward procedure to do in the office, but the company is extraordinarily good at working on the reimbursement. "I've never worked with a company that is more attuned to assistance with reimbursement than this company is. It's absolutely unparalleled."

To learn more

For more information about how the **Renessa** treatment may benefit your patients, call toll free 1-866-784-4777, e-mail info@novasys-medical.com or visit the company's website at www.novasysmedical.com.

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