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## **New Trial of Novasys Medical's *Renessa*® Treatment Studies Women Who Have Failed Previous Surgical Procedures for Stress Urinary Incontinence**

*Non-surgical treatment may offer new hope for women who continue to leak even after surgery*

NEWARK, CALIF., May 17, 2007 – Novasys Medical, Inc., a developer of innovative therapies in women's health, announced today that the first patients have been treated in a new, prospective, randomized, sham-controlled trial to evaluate the safety and effectiveness of its *Renessa*® treatment for stress urinary incontinence (SUI) in women who have had previous surgical procedures for their incontinence. The study, conducted under an Investigational Device Exemption (IDE) from the U.S. Food and Drug Administration (FDA), will enroll 250 women at 15 sites across the U.S. The Company anticipates using the results of the trial in an application to the FDA for an expanded indication for the *Renessa* treatment in women who have failed previous surgical intervention for SUI. The *Renessa* procedure is currently offered to women who have failed conservative therapy and are not candidates for, or who do not desire, a surgical procedure.

Rodney Appell, M.D., Professor of Urology at Baylor College of Medicine, is the Principal Investigator for the trial. According to Dr. Appell, "surgical procedures for SUI such as tension-free vaginal tape (TVT) and transobdurator tape (TOT) slings are very often successful, but as the popularity of these procedures increases, so does the number of women who experience suboptimal results ranging from improvement without cure to postoperative failure." Follow-up surgery can improve residual or recurrent symptoms but generally carries lower success rates and higher complication risks. As a result, many women are reluctant to undergo a second surgical procedure.

In 2006, there were nearly 400,000 women in the U.S. who underwent a surgical procedure for SUI, and this number is expected to continue to grow over the next several years. Studies show that approximately 20% of women continue to experience SUI symptoms after surgery. Over the next five years, an estimated 700,000 women will have had suboptimal results after surgery, representing an incremental \$600 million market opportunity for the *Renessa* treatment.

"Women who continue to experience urine leakage after undergoing a surgical procedure have few options available to them. We are looking forward to the results of this new trial to determine if the *Renessa* treatment may provide these women with a safe and effective non-surgical option to address their continuing SUI symptoms," said investigator Shawn Menefee, M.D., a urogynecologist with Kaiser Permanente in San Diego, California. Dr. Menefee treated the first patient in the trial.

SUI is the involuntary leakage of urine associated with laughing, coughing, sneezing and recreational activities. The condition is caused by a variety of factors, most commonly childbirth, and often restricts the social, professional, and personal lives of an estimated 15 million women in the U.S. alone. The FDA-cleared Renessa System includes a small probe which a physician passes through the natural opening of the urethra (transurethral). The probe heats multiple small treatment sites in the submucosa of the bladder neck and upper urethra, denaturing collagen in the tissue. Upon healing, the treated tissue is firmer, resulting in increased resistance to involuntary leakage at times of increased abdominal pressure, such as laughing, coughing or during exercise.

The Renessa treatment can be performed in the convenience of a physician's office using local anesthesia. There are no incisions, bandages or dressings required. Recovery is rapid and comfortable, with minimal post-procedure limitations.

### **About Novasys Medical**

Novasys Medical, Inc. is a privately held, venture-backed company which 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 (SUI).

For more information, please visit [www.novasysmedical.com](http://www.novasysmedical.com) or call (510) 226-4060.

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