

**FOR IMMEDIATE RELEASE**

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**Novasys Medical, Inc. Receives FDA Clearance for the Renessa™ System**

*Novel Non-Surgical Approach to Treat Female Stress Urinary Incontinence*

NEWARK, CALIF. – August 3, 2005 – Novasys Medical, Inc. announced today that its Renessa™ System has been cleared for marketing by the United States Food and Drug Administration (FDA) for the treatment of stress urinary incontinence (SUI) due to hypermobility in women who have failed conservative care and are not candidates for surgical therapy. The Renessa System offers women and their physicians a novel non-surgical approach to the treatment of SUI which can be performed in a physician's office or an outpatient center.

SUI is the involuntary leakage of urine associated with laughing, coughing, sneezing, sexual 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 9 million women in the U.S. alone.

“Many women with SUI prefer a non-surgical approach to treat their stress urinary incontinence. Until now, these approaches have required multiple treatments,” said Dr. Rodney Appell, Professor, Scott Department of Urology at the Baylor College of Medicine in Houston, Texas. “With the Renessa System, women now have a non-surgical treatment option which is performed one time, without incisions or general anesthesia, clearly benefiting SUI patients.”

FDA clearance of the Renessa System was based on outcomes of a 12 month, multicenter clinical trial involving more than 170 women at 10 sites nationwide. The study demonstrated the safety and efficacy of treatment with the Renessa System. Key 12 month clinical outcomes included:

- 76% of women experienced a reduction in daily incontinence episodes;
- 68% of women used fewer incontinence pads each day;
- 58% of women no longer used incontinence pads;
- 73% of women experienced a reduction in leak severity;
- 67% of women reported an improvement in their quality of life;
- 35% of women no longer leaked (became continent).

The Renessa treatment applies controlled heat to tissue targets within the lower urinary tract, denaturing collagen at multiple small treatment sites. Upon healing, these treated microscopic sites increase tissue resistance to involuntary leakage at times of increased intra-abdominal pressure, reducing or eliminating SUI episodes. A physician performs the procedure in approximately 20 minutes using a single-use transurethral probe. No visualization of the treatment site is required. The procedure requires no bandages or dressings, and women can safely resume most activities immediately following treatment.

The Novasys Medical direct sales force is introducing the Renessa System to gynecologists, urogynecologists, and urologists nationwide. “In working with leading urologists and gynecologists to develop the Renessa technology,” said Debra Reisenhel, president and chief executive officer of Novasys Medical, “we recognized a real need for an in-office or outpatient procedure that improves a woman’s quality of life without incisions, repeat treatments or recovery time. We are excited to introduce the Renessa System to meet the needs of women and the physicians who treat them.”

## **Treating Female Stress Urinary Incontinence**

While both surgical and non-surgical SUI therapies are currently available, most are associated with concerns regarding safety, recovery, compliance, and/or effectiveness. It is estimated that approximately 80% of women with SUI do not seek treatment of any kind due to concerns over complications or lack of confidence in the effectiveness of available options.

### **About Novasys Medical, Inc.**

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

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