

## **NOVASYS MEDICAL RECEIVES CE MARK FOR NOVASYS MICRO-REMODELING™ SYSTEM**

**NEWARK, California, April 22nd, 2003:** Novasys Medical, Inc., a developer of new therapies and technologies for the treatment of female pelvic disorders, today announced that it has received approval to affix the CE Mark to its Micro-remodeling™ System for female stress urinary incontinence. The CE Mark allows Novasys Medical, Inc to market the Micro-remodeling System in European Union countries and signifies that the product complies with all applicable safety and quality standards.

Per the CE mark approval, the Novasys Micro-remodeling™ System is indicated for the treatment of female genuine stress urinary incontinence (SUI) associated with bladder outlet hypermobility (BOH), with or without associated intrinsic sphincter deficiency (ISD). The Company estimates that there are more than 8 million women in the European Union who are potential candidates for the procedure.

"Receipt of the CE Mark is an important milestone for our company and validation of our technology," said Debra Reisenhel, President and CEO of Novasys Medical, Inc. "This is the first step toward the full launch of this highly anticipated non-surgical treatment." The Novasys Micro-remodeling™ System is currently not commercially available, but is under investigation in the United States. Novasys Medical recently completed the treatment phase of its randomized, controlled clinical trial and anticipates submitting its results to the FDA in 2003.

As many as 25 million Americans (of which at least 80% are women) suffer from bladder control problems. The most common incontinence problem for women is stress urinary incontinence, which is caused by weakening of the bladder outlet, resulting in the involuntary loss of urine during exercise, sneezing, coughing, laughing and other activities. While other treatments are available, most are either palliative or surgical.

The Novasys treatment utilizes a transurethral device to remodel microscopic regions of tissue within the bladder outlet and proximal urethra using radiofrequency energy (RF), increasing resistance to leakage without the need for surgery. Unlike RF energy tissue ablation, which shrinks tissue, RF energy tissue remodeling reduces tissue compliance through the denaturation of microscopic tissue targets without producing gross anatomical change.

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

Novasys Medical, Inc., a privately held, venture-backed company, develops novel solutions designed to better address significant health and lifestyle issues impacting women worldwide. The Company's initial focus is on the commercialization of a proprietary, non-surgical Radiofrequency device to treat 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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