



**RADIESSE™ INJECTABLE FILLER PROVIDES  
12-MONTH IMPROVEMENT OF VOCAL FOLD INSUFFICIENCY IN  
MULTICENTER CLINICAL VOICE STUDY**

*-- New Scientific Data Released at National Otolaryngology Meeting --*

**San Mateo, CA – May 25, 2006.** BioForm Medical, Inc. a leading medical device company that develops and commercializes injectable implant products for soft tissue augmentation announced the results of a rigorous clinical study confirming the long-term efficacy of Radiesse for the treatment of Vocal Fold Insufficiency. This common voice-altering condition is a serious form of voice loss in which one or both vocal folds (and cords) lack the physical capacity to vibrate properly. Radiesse treatment has demonstrated success in improving the voice of patients for 12 months without surgery.

Lead investigator and voice specialist Clark A. Rosen, M.D., presented new study data showing that 73% of study patients reported their voice was greatly or significantly improved 12 months after Radiesse treatment. The scientific findings were reported during the annual Combined Otolaryngology Spring Meetings (COSM) in Chicago on May 19-22, 2006.

“The data collected in this study is very beneficial for managing patients with vocal fold insufficiency because we can provide a long-lasting treatment option to patients who previously were resigned to live with their condition or have an ‘open’ neck surgery,” said Dr. Rosen, director of the University of Pittsburgh Voice Center. “So many patients suffer with voice problems that limit their quality of life because they don’t know that there are safe, simple treatment options which often can be done in the office.”

This investigation is the largest multi-center, open-label, prospective clinical study of its kind in the field of voice disorders. More than 100 patients were enrolled at 11 clinical centers in the United States and Europe. Most patients received one treatment with Radiesse, which was injected into the affected vocal fold(s) to modify the larynx and cause the vocal folds to meet at midline. Voice-related outcome measures were collected for pre-injection and at one, three, six and 12 months post-injection. Dr. Rosen noted that “these results are significant because they demonstrate Radiesse to be a safe, effective vocal fold augmentation material that can be injected in the office or operating room with excellent, long-term voice results.”

Radiesse is the first non-surgical vocal fold treatment that has proven 12 months of effectiveness in a rigorous clinical study of vocal fold insufficiency.

**Study Highlights**

Patients received treatment with Radiesse for two types of voice disorders: paralysis of the vocal folds in which one of the vocal cords doesn’t move to meet the middle opening between the two vocal folds; and glottal incompetence in which the two vocal cords move but are thin and weak

and don't meet together to close the middle opening completely (usually due to muscle damage or muscle loss associated with aging).

Key findings based on more than 50 study patients at the 12-month time point include:

- 73% of patients reported their voice was greatly or significantly improved 12 months after injection.
- The mean voice handicap index scores, a standard assessment tool used to measure vocal recovery, were improved at the 12-month follow-up time point.
- Objective voice testing of maximum phonation test, a measure of how long a person can say "ah" on one breath showed a statistically significant improvement comparing pre-treatment and the 12-month follow-up time points.

### **About Radiesse**

Manufactured and distributed in the U.S. by BioForm Medical, Inc., Radiesse is an injectable filler used in various cosmetic, reconstructive and ENT applications to augment and contour folds, depressions and vocal fold defects of the facial area. Composed of tiny calcium hydroxylapatite (CaHA) particles suspended in a water-based gel carrier, Radiesse has been proven safe and biocompatible in numerous soft tissue applications. Among the product's many advantages, Radiesse treatment allows steady growth of collagen matrix, produces virtually instant results, and lasts one to three years. For more information, please visit [www.radiesse.com](http://www.radiesse.com).

### **About BioForm Medical, Inc.**

Headquartered in San Mateo, CA, BioForm Medical, Inc., is a privately-held medical device company developing and commercializing injectable implant products for soft and hard tissue augmentation and topical preparations for dermatological conditions. The Company is dedicated to improving patients' lives by providing high quality, innovative, safe and effective medical products for use in the plastic surgery, dermatology, urology, and ENT markets. For more information about BioForm, please visit the Company's website at [www.bioformmedical.com](http://www.bioformmedical.com).

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