



NEWS RELEASE

FDA APPROVES RADIESSE® FACIAL FILLER FOR TWO NEW AESTHETIC INDICATIONS

Long-Lasting Filler from BioForm Medical Approved for Treatment of Facial Wrinkles and Folds; and for the Correction of HIV-Associated Facial Wasting

San Mateo, CA – December 27, 2006. BioForm Medical, Inc., a privately-held medical aesthetics company, today announced that the U.S. Food and Drug Administration (FDA) approved Radiesse®, the next-generation cosmetic dermal filler, for the long-lasting correction of moderate to severe facial wrinkles and folds such as nasolabial folds. Radiesse also received a second FDA approval for the long-lasting correction of facial fat loss (lipoatrophy) in people with human immunodeficiency virus (HIV).

Radiesse is the first filler with advanced calcium-based microsphere technology that not only provides volume replacement to wrinkles, folds and sunken depressions but also stimulates the body to produce new collagen. This unique action restores the fullness and contours of a youthful, healthy appearance with sustained results that last an average of one year or more.

“Today’s FDA approval of Radiesse for use in facial aesthetic applications confirms our rigorous clinical findings that Radiesse is safe and effective for long-term facial aesthetic enhancement,” said Steven L. Basta, President and Chief Executive Officer of BioForm. “With its advanced calcium-based microsphere technology, Radiesse is the first facial cosmetic filler with a proven 12 month benefit in multiple clinical studies. Accordingly, Radiesse is raising the bar to become the new standard for the treatment of facial wrinkles and folds such as nasolabial folds.”

Radiesse is composed of calcium hydroxylapatite microspheres in a water-based gel carrier. Radiesse provides immediate improvement so a patient looks better the moment the product is injected. The calcium microsphere technology also enables the body to generate new collagen, providing longer lasting effects than other available fillers. Further, because Radiesse is a robust, full-bodied material, it provides physicians a superior level of control, predictability and finesse for facial applications.

“The approval of Radiesse ushers in a new era in the non-surgical management of facial aging because it both ‘volumizes’ facial folds and rebuilds the skin’s foundation to restore a youthful facial appearance for our patients,” said Lawrence Bass, M.D., Clinical Assistant Professor of Plastic Surgery; Director, Minimally Invasive Plastic Surgery Program, New York University

Medical Center, New York, NY, and investigator for Radiesse pivotal trials. “Our findings from the pivotal clinical trial and those of a separate clinical study comparing the long-term efficacy of Radiesse with the leading hyaluronic acid product demonstrate clear advantages that make Radiesse the preferred treatment option for the correction of nasolabial folds.”

FDA approval of Radiesse for treatment of facial wrinkles and folds was based on the results of a pivotal clinical trial supporting Radiesse’s safety and effectiveness.

About the Nasolabial Fold Study

In the pivotal study, conducted at four medical centers in the United States, 117 patients with nasolabial folds were treated with Radiesse on one side of the face and a control agent (Cosmoplast®, a human collagen product) on the other. Results based on ratings of three blinded evaluators showed that six months after treatment, Radiesse was more effective than the control on every comparative efficacy outcome ($p < 0.0001$).

Key clinical findings include:

- 82 percent of nasolabial folds treated with Radiesse showed improvement after six months. This was significantly higher than the control which showed improvement in only 27 percent of treated folds ($p < 0.0001$).
- After six months, the fold treated with Radiesse was more improved in 79 percent of patients compared to the control treated fold. The folds treated with the control rated more improved in only 5 percent of patients.
- The nasolabial folds treated with Radiesse required approximately half as much volume (1.22cc) than the folds treated with the control. (2.35cc).
- Both products were safe and well tolerated, with no serious adverse events reported. In the 117 patients treated, Radiesse had zero granulomas and the same low rate of nodules as the control.

About Radiesse

Radiesse is a longer-lasting injectable dermal filler used in many cosmetic, reconstructive and therapeutic applications to augment soft tissue, such as facial wrinkles, folds and contours. Composed of calcium hydroxylapatite (CaHA) microspheres suspended in an aqueous gel, FDA-approved Radiesse both fills and stimulates the body to produce new collagen for immediate results that last about one year or more. As such, next generation Radiesse is setting a new standard for the correction of nasolabial folds. Manufactured and distributed by BioForm Medical, Inc., Radiesse has been proven safe and effective in hundreds of thousands of procedures worldwide. For more information about Radiesse, please visit www.radiesse.com

About BioForm Medical, Inc.

BioForm Medical, Inc. is a privately-held medical aesthetics company headquartered in San Mateo, California. BioForm is dedicated to bringing doctors and their patients safe and

effective products for use in the dermatology, ENT, and plastic surgery markets. BioForm's products include Radiesse[®], the first 12-month filler for use in facial aesthetics and vocal fold insufficiency; Cutanix[®] for facial redness associated with conditions such as rosacea; a new surgical adhesive product for plastic surgery applications being developed in a partnership with CryoLife Inc.; and Coaptite[®] for treating female stress urinary incontinence ("SUI") which is marketed through a partnership with Boston Scientific Corporation. For more information about BioForm, please visit www.bioformmedical.com

EDITOR'S NOTE: B-Roll videotape, including animation of how Radiesse works, treatment footage and before and after visuals, is available upon request.

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