



MERZ NORTH AMERICA ANNOUNCES THE AVAILABILITY OF RADIESSE® (+) WITH INTEGRAL 0.3% LIDOCAINE

Radiesse® (+) provides immediate lift with enhanced comfort¹

RALEIGH, N.C. – MARCH 16, 2015 – BUSINESS WIRE – [Merz North America](#), US affiliate of the global Merz Pharma Group, announces that [Radiesse® \(+\)](#) with integral 0.3% Lidocaine (“Radiesse® Plus“) has received FDA approval and is now available to US physicians. Radiesse® (+) provides the immediate lift of wrinkles and folds, stimulation of natural collagen production, and the lasting results that patients and physicians expect from Radiesse®, as well as providing patients significant reduction in pain due to the addition of lidocaine¹⁻⁴.

Radiesse® (+) injectable implant is an opaque, dermal filler that contains a small quantity of local anesthetic (lidocaine). Radiesse® (+) is indicated for subdermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

“With the introduction of Radiesse® (+), Merz addresses the need of restoring lost facial volume while reliably enhancing patient comfort and eliminating the need for in-office lidocaine mixing. We are excited to provide our physician customers with yet another Merz technology to help deliver positive patient outcomes and treatment experiences,” stated Jim Hartman, Vice President and Head of U.S. Aesthetics/OTC for [Merz North America](#).

“In my practice, comfort during treatment is a concern for the majority of the patients that walk through the door,” stated [Dr. Z. Paul Lorenc, MD, FACS](#). “Radiesse (+) allows physicians to treat/correct wrinkles and folds with the same effective product we’ve used for the past decade, while providing patients with the enhanced comfort they are looking for.” In addition to his work as a board-certified aesthetic plastic surgeon in private practice in New York City, Dr. Lorenc is actively involved in research, development and advancement of new aesthetic surgical and non-surgical techniques and procedures.

Radiesse® (+) is a robust filler providing high elasticity (G') and viscosity¹. In a clinical study, 101 patients received Radiesse® on one side of the face and Radiesse® (+) on the other side of the face. Patients rated their pain on a scale of 0 to 10. On the scale, 0 was no pain and 10 was very severe pain. Immediately

¹ Data on file

² IFU Radiesse® Lidocaine

³ Sundaram H, Voigts B, Beer K, Meland M. Comparison of the rheological properties of viscosity and elasticity in two categories of soft tissue fillers: calcium hydroxylapatite and hyaluronic acid. *Dermatol Surg.* 2010;36 (suppl 3):1859-1865.

⁴ Berlin AL, Hussain M, Goldberg DJ. Calcium hydroxylapatite filler for facial rejuvenation: a histologic and immunohistochemical analysis. *Dermatol Surg.* 2008;34 (suppl 1):S64-S67.

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after injection, patients rated their pain about 6.7 on a scale of 0 to 10 for the side of the face injected with Radiesse[®] compared to about 2.3 on the same scale for the side of the face treated with Radiesse[®] (+). Sixty (60) minutes after treatment, patients rated their pain about 1.1 on a scale of 0 to 10 for the side of the face injected with Radiesse[®] compared to about 0.3 on the same scale for the side of the face treated with Radiesse[®] (+).

About RADIESSE[®] (+)

Radiesse[®] is an opaque dermal filler that contains a small quantity of local anesthetic (lidocaine). Radiesse[®] (+) temporarily adds volume to help smooth moderate to severe facial wrinkles and folds, such as nasolabial folds (the creases that extend from the corner of your nose to the corner of your mouth). Radiesse[®] (+) is composed of calcium hydroxylapatite (CaHA) microspheres suspended in a water-based gel carrier.

About Merz Aesthetics

Merz Aesthetics is a division of Merz North America, a specialty healthcare company that develops and commercializes treatment solutions in aesthetics, dermatology and neurosciences in the U.S. and Canada. As part of the Merz Pharma Group of companies, our ambition is to become the most admired, trusted and innovative aesthetics and neurotoxin company. By developing products that improve patients' health and help them to live better, feel better and look better, Merz will continue to make significant contributions to the well-being of individuals around the world. Merz Aesthetics is an important contributor to the U.S. aesthetics space, offering a well-balanced product portfolio that includes the dermal fillers Radiesse[®] and Belotero Balance[®]. For more information about Merz Aesthetics and their U.S. product portfolio, please visit www.merzusa.com.

RADIESSE is a registered trademark of Merz North America, Inc. BELOTERO is a registered trademark and Merz Aesthetics is a registered trademark of Merz Pharma GmbH & Co. KGaA.

RADIESSE[®] (+) IMPORTANT SAFETY INFORMATION

Contraindications: RADIESSE (+) injectable implant is contraindicated for patients with known hypersensitivity to any of the components, severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies; and patients with bleeding disorders.

Warnings: Use of RADIESSE (+) in any person with active skin inflammation or infection in or near the treatment should be deferred until the inflammatory or infectious process is controlled. Do not overcorrect (overfill) a contour deficiency with RADIESSE (+) because the depression should gradually improve within

several weeks as the treatment effect of RADIESSE (+) occurs. The safety and effectiveness for use in the lips has not been established.

Precautions: RADIESSE (+) contains calcium hydroxylapatite, radiopaque particles, that are visible on CT Scans and may be visible in standard radiography. Patients using medications that can prolong bleeding, such as aspirin or warfarin, may experience increased bruising or bleeding at the injection site.

Patients should minimize exposure of the treated area to extensive sun or heat exposure for approximately 24 hours after treatment or until any initial swelling and redness has resolved. RADIESSE (+) is for Single Patient Use Only. Do not use if needle is bent. Do not re-shield used needles. Discard needles and syringes as potential biohazards.

Safety of RADIESSE (+) beyond 3 years; in the periorbital area; with concomitant dermal therapies or other drugs or implants; in patients with susceptibility to keloid formation and hypertrophic scarring; in pregnancy, in breastfeeding females or in patients under 18 years has not been established. As with all skin-injection procedures, there is a risk of infection with RADIESSE (+). Patients with a history of herpetic eruption may experience reactivation of herpes.

Adverse Events: The most common serious adverse events with RADIESSE include necrosis, allergic reaction, edema and infection. Common adverse events with RADIESSE are generally mild in nature and short in duration and include bruising, redness, swelling, pain, itching and other local side effects. To report a problem with RADIESSE, please call Customer Service at 1.866.862.1211.

[For Instructions for Use Document and complete Patient Information Guide, please click here.](#)

Caution: Rx only.

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