



## MERZ NORTH AMERICA ANNOUNCES FDA APPROVAL OF RADIESSE® FOR USE IN THE HANDS

***Radiesse® is the first and only dermal filler approved by the FDA for  
correction of hand volume loss***

RALEIGH, N.C. – JUNE 4, 2015 – BUSINESS WIRE – [Merz North America](#), US affiliate of the global Merz Pharma Group, announces that Radiesse® has received U.S. FDA approval for hand augmentation to correct volume loss in the dorsum of the hands. Radiesse® provides an immediate volumizing effect and can help to reduce the prominence of tendons and veins in the hands<sup>1</sup>, delivering smooth, natural-looking results that can last up to 1 year.

“Merz is proud to be able to provide patients and physicians with the first and only dermal filler approved by the FDA for use in the hands,” stated Jim Hartman, Vice President and Head of U.S. Aesthetics/OTC for [Merz North America](#). “Market research tells us that attention to the aesthetic appearance of hands has increased in recent years, particularly among individuals who have undergone facial rejuvenation procedures<sup>2</sup>. This new indication for Radiesse® is a result of our focus on meeting unmet needs in the US aesthetics market, and we are excited to provide our physician customers with this new option to better fulfill the aesthetic desires of their patients.”

“In recent years, I’ve seen an increase in the number of patients who are seeking aesthetic treatments for their hands. With Radiesse® for hands, I am thrilled to be able to provide an FDA-approved treatment for patients in my practice who are ready for this next step in their aesthetic regimen,” stated [Dr. Amir Moradi](#). “Volumizing the hands with Radiesse® allows me to enhance my patients’ overall appearance and provides the opportunity to finally rejuvenate both their hands and their faces.” Dr. Moradi is a board-certified facial plastic and reconstructive surgeon in private practice in San Diego, California. Serving the community and his peers is a top priority for Dr. Moradi; his work outside of the practice includes volunteering, speaking, training, and consulting.

In a randomized, controlled US trial, blinded evaluators reported that Radiesse® improved the appearance of both hands in 75% of treated patients at 3 months. Importantly, 98% of treated patients also reported improvement in the appearance of their hands at 3 months. Improved aesthetic outcomes as measured on the Global Aesthetic Improvement Scale (GAIS) after initial and repeat treatments correlating with clinical improvement were demonstrated in this study, with all primary and secondary endpoints being met. Most adverse events were injection

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<sup>1</sup> Busso M et al. Multicenter, Randomized Trial Assessing the Effectiveness and Safety of Calcium Hydroxylapatite for Hand Rejuvenation. *Dermatol Surg.* 2010;36:790-797. Harris Poll 2014

<sup>2</sup> Harris Poll, 2014

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site reactions such as swelling, redness, pain and bruising, which were usually mild to moderate, short in duration (lasting about 1 week), and required no treatment. No severe device-related adverse events were reported that required treatment.

#### **About RADIESSE® for Hands**

Radiesse® is an opaque dermal filler composed of calcium hydroxylapatite (CaHA) microspheres suspended in a water-based gel carrier. Radiesse® temporarily adds volume in the hands, to help correct volume loss in the hands. In addition to its indication for use in the hands, Radiesse® is indicated for subdermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

#### **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®. To learn more about Merz's full aesthetic portfolio, including their full line of aesthetic injectables, the energy-based Ultherapy® system and the **NEOCUTIS** skincare line, please visit [www.merzusa.com/aesthetics-otc](http://www.merzusa.com/aesthetics-otc).

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

#### **RADIESSE® IMPORTANT SAFETY INFORMATION:**

##### **Indication:**

RADIESSE® injectable implant is FDA-approved for hand augmentation to correct volume loss in the dorsum of the hands.

**Contraindications:** RADIESSE injectable implant is contraindicated for patients with severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies; patients with known hypersensitivity to any of the components; and patients with bleeding disorders. (1)

**Warnings:** Introduction of product into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft tissue fillers, for example inject the product slowly and apply the least amount of pressure necessary. Rare but serious adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate health care practitioner specialist should an intravascular injection occur.

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.

Special care should be taken to avoid injection into veins or tendons in the hand. Injection into tendons may weaken tendons and cause tendon rupture. Injection into veins may cause embolization or thrombosis. Injection into the hand may cause adverse events that last for more than 14 days. Injection in the dorsum of the hand may result in temporary difficulty performing activities (48% of study patients reported this adverse event). Fitzpatrick Skin Types IV-VI may have an increased risk in difficulty performing activities (68% of Fitzpatrick Skin Types IV-VI reported this event). RADIESSE may cause nodules, bumps or lumps in the dorsum of the hand (12% reported this event) and can last up to a 1 year.

Injection into patients with very severe loss of fatty tissue with marked visibility of veins and tendons has not been studied. The safety and effectiveness in this patient population has not been established.

Volumes over 3 cc of RADIESSE per hand in a treatment session have not been studied. Increased bruising is associated with higher volume injection. Retreatment with RADIESSE of volumes greater than approximately 1.6cc per hand in a treatment session can result in increased adverse events (redness, pain, swelling, and difficulty performing activities).

Use of RADIESSE in the dorsum of the hand in patients with diseases, injuries or disabilities of the hand has not been studied. Extreme care should be used in

treating patients with autoimmune disease affecting the hand, hand implants, Dupuytren's contracture, history of hand tumor, vascular malformations, and patients at risk for tendon rupture

**Precautions:** In order to minimize the risk of potential complications, this product should only be used by healthcare practitioners who have appropriate training, experience and who are knowledgeable about the anatomy at and around the injection site. In order to minimize the risks of potential complications, Healthcare practitioners should fully familiarize themselves with the product, the product educational materials and the entire package insert.

RADIESSE contains calcium hydroxylapatite (CaHA) particles that are radiopaque and are clearly visible on CT Scans and may be visible in standard, plain radiography. Safety of RADIESSE injectable implant beyond 3 years in the face and 1 year in the hand has not been investigated in clinical trials.

As with all transcutaneous procedures, RADIESSE injectable implant injection carries a risk of infection.

Use of RADIESSE in the dorsum of the hand in patients with diseases, injuries or disabilities of the hand has not been studied. Care should be used in treating patients with autoimmune disease affecting the hand, hand implants, Dupuytren's contracture, history of hand tumor, vascular malformations, Raynaud's disease and patients at risk for tendon rupture.

Use of RADIESSE in the dorsum of the hand may result in significant swelling of the dorsum of the hand. Patients should be instructed to remove jewelry (rings) before treatment and until swelling has resolved to avoid compromise of finger circulation. The effects of RADIESSE injection on hand function is uncertain.

Patients who are using medications that can prolong bleeding, such as aspirin or warfarin, may experience increased bruising or bleeding at the injection site.

Patients should inform their physician if they are using such medications. Interactions between RADIESSE with drugs or other substances or implants have not been evaluated. (7)

Safety of RADIESSE for use during pregnancy, in breastfeeding has not been established. Safety of RADIESSE injected into the dorsum of the hand in patients under 26 years old and over 79 years old has not been studied. The safety of RADIESSE in patients with increased susceptibility to keloid formation and hypertrophic scarring has not been studied. The safety of RADIESSE injectable implant with concomitant dermal therapies such as epilation, UV irradiation, or laser, mechanical or chemical peeling procedures has not been evaluated in controlled clinical trials. No studies of interactions of RADIESSE injectable implant with drugs or other substances or implants have been conducted.

Patients with a history of previous herpetic eruption may experience reactivation of the herpes.

Patients should minimize strenuous activity and 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.

**Adverse Events:** The most common serious adverse events that have been seen with Radiesse regardless of indication include necrosis, allergic reaction, edema and infection. Common adverse events with Radiesse when injected into the dorsum of the hand include bruising, redness, swelling, pain, itching, nodule or bumps/lumps, difficulty performing activities, loss of sensation and other local side effects. To report a problem with Radiesse, please call Customer Service at 1-866-862-1211.

[Click here to view the full Instructions for Use for Radiesse® for Hands.](#)

[Click here to view the Patient Information Guide for Radiesse® for Hands.](#)

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