

## Important Safety Information for RADIESSE® Volumizing Filler

**Indication:** RADIESSE® Volumizing Filler is FDA-approved for subdermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

**Contraindications:** RADIESSE® Volumizing Filler should not be used in patients with bleeding disorders or in patients with severe allergies manifested by a history of anaphylaxis, with a history or presence of multiple severe *allergies or with a history of hypersensitivity to the components of RADIESSE® Volumizing Filler.*

**Warnings:** RADIESSE® Volumizing Filler should not be injected into blood vessels. Use of RADIESSE® Volumizing Filler in any person with active skin inflammation or infection in or near the treatment area should be deferred until the inflammatory or infectious process has been controlled. The safety and effectiveness for use in the lips has not been established. There have been published reports of nodules associated with the use of RADIESSE® Volumizing Filler injected into the lips.

**Precautions:** Safety for use during 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. Patients using medications that prolong bleeding, such as aspirin or warfarin, may, as with any injection procedure, experience increased bruising and bleeding at the injection site. Patients should inform their physician if they are using such medications. 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. Safety and effectiveness in the periorbital area has not been established. The safety of RADIESSE® Volumizing Filler in patients with a susceptibility to keloid formation and hypertrophic scarring has not been studied. Patients with a history of previous herpetic eruption may experience reactivation of the herpes.

**Adverse Events:** After injection, patients may experience redness, bruising, swelling or other local side effects. Most side effects of treatment resolve within a few days. More rare side effects may include swelling that lasts longer, unevenness or firmness in the area injected.

**Important:** For full safety information, please visit [www.Radiesse.com](http://www.Radiesse.com) or call Merz Aesthetics Customer Service at 866-862-1211

**Caution:** Rx Only