

Radiesse Informed Consent

I, _____ understand that I will be injected with Radiesse Volumizing Filler into the following areas. _____.

Radiesse Volumizing Filler is a restorable implant product approved by the United States Food and Drug Administration for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

Risks and complications that may be associated with Radiesse and the implant procedure include but are not limited to:

1. Facial bruising, redness, swelling, itching and pain: I understand that there is a risk of bruising, redness, swelling, itching and pain associated with the procedure. These symptoms are usually mild and last less than a week, but can last longer. Patients who are using medications that can prolong bleeding, such as aspirin, warfarin, or certain vitamins and supplements, may experience increased bruising or bleeding at the injection site.
2. Nodule and palpable material: I understand that there is a risk that small lumps may form under my skin due to the filler collecting in one area. I also understand that I may be able to feel the filler material in the area where it has been injected. Any foreign material injected into the body can create the possibility of swelling or other local reactions.
3. Nodules in Lips: I understand that Radiesse should not be injected into the lips. There have been published reports of nodules associated with the use of Radiesse injected into the lips.
4. Migration: I understand that Radiesse, as with any filler material, may move from the place where it was injected.
5. Infection: As with all transcutaneous procedures, I understand that the injection of any filler material may carry the risk of infection.
6. History of Herpes Infection: I understand that there is a risk, that injection of any filler material carries the risk of a recurrence outbreak of herpes (fever blisters/cold sores/shingles) and that the outbreak may be severe in nature. I have disclosed to the medical provider my medical history, and in particular, disclosed my herpes outbreaks.
7. Allergic Reactions: I understand that Radiesse Volumizing Filler should not be used in patients with severe allergies, a history of anaphylaxis, or hypersensitivity to any of the ingredients in Radiesse.
8. Keloids/Scarring: I understand that the safety of Radiesse in patients with known susceptibility to keloid formation or hypertrophic scarring has not been studied.
9. Accidental Injection into a blood vessel: I understand that Radiesse can be accidentally injected into a blood vessel, which may block the blood vessel and cause local tissue damage, or potentially a heart attack or stroke.
10. Radio-opacity- I understand that Radiesse is radio-opaque and is visible on CT scans and may be visible in X Rays.

11. Duration of Effect- I understand that the outcome of treatment with Radiesse will vary among patients. In some instances, additional treatments may be necessary to achieve the desired outcome.
12. Concomitant Dermal Therapies: I understand that the safety of Radiesse with concomitant dermal therapies such as epilation, UV irradiation, or laser, mechanical or chemical peeling procedures has not been evaluated in controlled clinical trials. The application of laser or other energy-based treatment within weeks of a Radiesse treatment is not recommended; as such treatments may alter the characteristics of Radiesse. If laser treatment, chemical peeling or other procedure based on active dermal response is considered after treatment with Radiesse, there is a possible risk of eliciting an inflammatory reaction at the injection site.

No studies of interactions of Radiesse with drugs or other substances have been conducted.

This above list is not meant to be inclusive of all possible risks associated with Radiesse, as there are both known and unknown side effects and complications associated with any medication or dermal filler injection procedure. I understand that medical attention may be required to resolve complications associated with my injection.

I understand that I should minimize exposure of the treated area to the sun or heat for approximately 24 hours after treatment or until any initial swelling or redness goes away.

The safety of Radiesse for use during pregnancy or in breastfeeding women has not been established.

I have discussed the potential risks and benefits of Radiesse with my doctor. I understand that there is no guarantee of any particular results of any treatment.

I understand and agree that all services rendered will be charged directly to me, and I am personally responsible for payment. I further agree, in the event of non-payment, to bear the cost of collection, and/or court costs and responsible legal fees, should they be required. By signing below, I acknowledge that I have read the foregoing informed consent, have had the opportunity to discuss any questions that I have with my doctor to my satisfaction, and consent to the treatment described above with its associated risks. I understand that I have the right not to consent to this treatment and that my consent is voluntary. I hereby release the doctor, the person performing the Radiesse filler injection and the facility from liability associated with this procedure.

Patient Signature

Date

Witness Signature

Date