Stacey Folk, MD
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Radiesse® Informed Consent

Radiesse® is a resorbable 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 may 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. Nodules and Palpable Material: I understand that there is a risk that small lumps may form under the skin due to the Radiesse® material collecting in one area where the material has been injected. Any foreign material injected into the body may create the possibility of swelling or other local reactions to a filler material.

3. Migration: I understand that the Radiesse®, as with any filler material, may move from the place where it was injected.

4. Infection: As with all transcutaneous procedures, I understand that the injection of any filler material carries the risk of infection.

5. Allergic Reactions: I understand that Radiesse® should not be used in patients with severe allergies, a history of anaphylaxis, or a history or presence of multiple severe allergies or hypersensitivity to any of the ingredients in Radiesse®.

6. Keliods/Scarring: I understand that the safety of Radiesse® in patients with known susceptibility to keloid formation or hypertrophic scarring has not been studied.

7. 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 even a heart attack or stroke.

8. Radio-pacity: I understand that Radiesse® is radioplaque and is visible on a CT scans and may be visible in X-rays.

9. Duration of effect: I understand that the outcome of treatment with Radiesse® will vary among

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patients. In some instances additional treatments may be necessary to achieve the desired outcome.

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

This above list is not meant to be inclusive of all possible risks associated with Radiesse® or dermal fillers in general, 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 after the 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 reasonable 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 completely voluntary. I hereby release the doctor, the person performing the Radiesse® injections and the facility from liability associated with this procedure.

I CONSENT TO THE TREATMENT OF RADIESSE AND I HAVE READ THE ABOVE LISTED ITEMS. I AM SATISFIED WITH THE INFORMED CONSENT PROCESS

_____ _____
Patient or Person Authorized to Sign for Patient Date

_____ _____
Witness Date