

INFORMED CONSENT FOR RADIESSE® TREATMENT

I _____ understand that I will be injected with RADIESSE® dermal filler in some or all of the areas: **Mid to lower face, Malar (Cheeks), Nasolabial Folds, Marionette Lines, Pre-Jowl** and other areas as determined necessary.

RADIESSE® dermal filler 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. Correction is temporary; therefore, touch-up injections as well as repeat injections are usually needed to maintain optimal correction. Less material (about half the amount) is usually needed for repeat injections. Most patients need one or possibly two treatments to achieve optimal wrinkle smoothing. The results may last as long as nine months to one year.

Risks and complications that may be associated with RADIESSE® dermal filler 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. Nodules, and Palpable Material: I understand that there is a risk that small lumps may form under my skin due to the RADIESSE® filler material collecting in one area. I also understand that I may be able to feel the RADIESSE® filler material in the 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® dermal filler, as with any filler material, may move from the place where it was injected.

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

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

6. Keloids/Scarring: I understand that the safety of RADIESSE® dermal filler 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® dermal filler 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-opacity: I understand that RADIESSE® dermal filler is radio-opaque and is visible on CT Scans and may be visible in x-rays.

9. Duration of Effect: I understand that the outcome of treatment with RADIESSE® dermal filler will vary among patients. In some instances, additional treatments may be necessary to achieve the desired outcome.

No studies of interactions of RADIESSE® dermal filler with drugs or other substances or implants have been conducted.

Contraindications

Radiesse injectable should not be used if you have:

- Severe allergies marked by a history of anaphylaxis or history or presence of multiple severe allergies

The following are important treatment considerations for you to discuss with us and understand in order to help avoid unsatisfactory results and complications:

- **Please inform us prior to treatment:** If you are using substances that can prolong bleeding, such as aspirin, Ibuprofen or other NSAIDS, Motrin, Fish Oils Vitamin E or Anticoagulants, as with any injection, you may experience increased bruising or bleeding at the injection site.
- **Please inform us prior to treatment:** If you are on immunosuppressive or therapy used to decrease the body's immune response, such as steroids as there may be an increased risk of infection.
- **Please inform us prior to treatment:** If you are pregnant or breast feeding.
- **Please inform us prior to treatment:** If you have history of excessive scarring (eg, keloid formations) and pigmentation disorders.

This above list is not meant to be inclusive of all possible risks associated with RADIESSE® dermal filler 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 any initial swelling or redness goes away.

The safety of RADIESSE® dermal filler for use during pregnancy or in breastfeeding women has not been established and is not recommended.

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

Patient's Acceptance of Risks

I have read the above information and have discussed it with my physician. I understand that it is impossible for the doctor to inform me of every possible complication that may occur. No guarantees about results have been made. By signing below, I agree that my doctor has answered all of my questions and that I understand and accept the risks, and alternatives of RADIESSE®.

I understand the information on this form is essential to determine my medical and cosmetic needs and the provision of treatment. I understand that if any changes occur in my medical history/health I will report it to the office as soon as possible. I acknowledge that all answers have been recorded truthfully and will not hold any staff member responsible for any errors or omissions that I have made in the completion of this form.

I have read and understand all information presented to me before signing this consent. I have had ample opportunity to ask any questions regarding RADIESSE® treatment, side effects and after care.

Client/Guardian Signature _____ Date _____

Staff Signature _____ Date _____