RADIESSE® Treatment Informed Consent

I, _____ understand that I will be injected with RADIESSE Volumizing Filler in the following areas: _____
_____.

RADIESSE® Volumizing 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.

Risks and complications that may be associated with RADIESSE Volumizing 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. **Nodules in Lips:** I understand that RADIESSE Volumizing Filler should not be injected in the lips. There have been published reports of nodules associated with the use of RADIESSE Filler injected in the lips.
4. **Migration:** I understand that the RADIESSE Volumizing Filler, as with any filler material, may move from the place where it was injected.
5. **Infection:** As with all transcutaneous procedures, I understand that injection of any filler material carries 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 of an outbreak of herpes (fever blisters/cold sores/shingles) and that the outbreak may be severe in nature. I have disclosed to the health care provider my medical history and, in particular, disclosed prior 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 history or presence of multiple severe allergies or hypersensitivity to any of the ingredients in RADIESSE Filler.
8. **Keloids/Scarring:** I understand that the safety of RADIESSE Volumizing Filler 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 Volumizing 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.

10. **Radio-opacity:** I understand that RADIESSE Volumizing Filler 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 Volumizing Filler 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 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. The application of laser or other energy-based treatments within weeks of RADIESSE treatment is not recommended as such treatments may alter the characteristics of RADIESSE injectable implant. If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with RADIESSE injectable implant, there is a possible risk of eliciting an inflammatory reaction at the implant site. This also applies if RADIESSE injectable implant is administered before the skin has healed completely after such a procedure.

No studies of interactions of RADIESSE Volumizing Filler 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 Volumizing 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 Volumizing Filler for use during pregnancy or in breastfeeding women has not been established.

I have discussed the potential risks and benefits of RADIESSE Volumizing Filler 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 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