

INFORMED CONSENT – RADIESSE® INJECTION

Pre-Treatment

No Aspirin, Advil, Aleve

Instructions

This is an informed-consent document which has been prepared to help your injector inform you concerning a number of available facial tissue filler injection therapies, their risks, and alternative treatments.

This consent covers injection using:

Radiesse® injectable implant is a sterile, latex-free, non—pyrogenic, semi-solid, cohesive implant. The principal component is synthetic calcium hydroxylapatite, suspended in a gel carrier that consists primarily of water (sterile water for injection USP), glycerin (USP) and sodium carboxymethylcellulose (USP). The gel is dissipated in vivo and replaced with soft tissue growth, while the calcium hydroxylapatite remains at the site of injection. The result is long-term yet non-permanent restoration and augmentation. It is FDA-approved for the correction of moderate to severe facial wrinkles and folds, and for the correction of the signs of facial lipoatrophy (fat loss).

Indication

Radiesse® injectable implant is indicated for

- The treatment of nasolabial folds
- The augmentation of cheeks
- The treatment of marionette lines
- The treatment of jawline
- The hand augmentation to correct volume loss in the dorsum of the hands
- The restoration and/or correction of the signs of facial fat loss

Normal Occurrences During Injection

*Bleeding *Bruising *Swelling *Pain

Specific Risks of Injections

*Needle Marks *Acne-Like *Skin Eruptions *Skin Sensitivity *Redness *Under/Over correction
*Asymmetry *Damage to Deeper Structure *Skin Lumpiness *Visible Tissue Filler Material *Granulomas
*Migration of Filler *Skin Necrosis *Allergic Reactions and Hypersensitivity *Drug and Local Anesthetic Reactions *Antibodies to Fillers *Accidental Intra-Arterial Injection *Scarring *Unsatisfactory Results

Unknown Risks: The long-term effect of facial fillers beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of facial filler as a soft tissue filler may be discovered.

Combination of Procedures: In some situations, Botox® injections or other types of tissue filler materials may be used in addition to facial filler in order to specifically treat areas of the face or to enhance the outcome from tissue filler therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with facial filler is unknown.

Pregnancy and Nursing Mothers: Animal reproduction studies have not been performed to determine if Hyaluronic Acid Filler or other facial fillers could produce fetal harm. It is not known if Hyaluronic Acid Filler or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive Hyaluronic Acid Filler or other facial filler treatments.

Drug Interactions: It is not known if facial filler reacts with other drugs within the body.

Long-Term Effects: Facial filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the facial filler material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing facial filler treatment (injections) is necessary in order to maintain the effect of the Filler. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to Facial Filler injections. Future surgery or other treatments may be necessary. Facial filler injection does not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

Post Treatment

Massage the treated area for 3 minutes, 3 times a day, for 3 weeks

ACKNOWLEDGMENT:

My questions regarding the procedure have been answered satisfactorily. I understand the procedure and accept the risks. I hereby release _____ (individual) and Facial Techniques (facility) and _____ (doctor) from all liabilities associated with the above indicated procedure.

Client Signature _____ Date _____

Witness Name(print) and Signature _____ Date _____

Physician Name (print) and Signature _____ Date _____