

## **RADIESSE (FORMERLY RADIANCE) TISSUE AUGMENTATION CONSENT**

### **A. Purpose and Background**

You have requested injection of Radiesse; a stabilized calcium hydroxylapatite suspension used for the treatment of facial folds and wrinkles as well as augmentation of the appearance of the lip. All medical and cosmetic procedures carry risks and may cause complications. This document is to make you aware of the nature of the procedure and its risks in advance so that you can decide whether to go forward with the procedure.

Radiesse is cleared by the FDA for marketing for maxillofacial and vocal cord augmentation ("on-label" use).

### **B. Procedure**

This product is administered via a syringe injection into the area of the face where the appearance is to be filled or augmented with Radiesse. An anesthesia (numbing medicine) may be used to reduce the discomfort of these injections. The area being treated may be iced prior to injection to reduce the risk of swelling with treatment. The area being treated will first be cleansed with an antiseptic. Radiesse is a tissue augmentation product that will be injected under the skin using a fine gauge needle. The depth of each injection will vary depending on the area and severity of wrinkle being treated or feature being augmented. Multiple injections may be required to achieve the desired cosmetic result. Following injection, the injector will massage the areas treated to even the contour of the treated area with the surrounding tissues. Ice may be applied after injection to reduce any swelling that may result from the treatment. After the initial treatment, repeat injections may be required for desired cosmetic results. Periodic touch-up injections may help sustain the desired level of correction.

### **C. Risks/Discomfort**

Since Radiesse relies on the body's own collagen production for its lasting cosmetic effect, some loss of correction may occur during the first two weeks following injection. This usually returns to the desired cosmetic level as the body produces new collagen to replace the Radiesse that is broken down. If more correction is desired after 4 to 6 weeks, additional material can be injected to increase the cosmetic effect.

Although a fine needle is used and Radiesse is generally considered safe, some complications may occur. These could include: swelling, pain, itching, or bruising at the injection site. These typically last no more than a day or two but may persist for longer periods in some individuals. As with any injection, there is a small risk of infection. This is mitigated by using sterile material and maintaining good technique including cleaning the skin before treatment. Some visible lumps may be visible after injection. These can usually be massaged away but in rare instances may require treatment with injectable medication or surgical removal. If you are considering laser treatment, chemical peels or other skin procedures, there is a risk of inflammatory reaction at the injection site if the skin has not yet completely healed. After treatment you should minimize exposure to UV lamps or bright sunlight or heat until any initial swelling has resolved.

Radiesse should not be used if you are pregnant. In some people with a history of cold sores or recurrent herpes simplex virus (HSV) infections, these conditions can be reactivated following injection of Radiesse. You should make sure your doctor is aware if you have this condition, as medication is available to prevent such outbreaks.

Radiesse is a calcium based compound and is visible on x-rays. This has not been shown to interfere with dental or diagnostic x-rays but may be reported by the radiologist as an abnormal finding.

**RADIESSE (FORMERLY RADIANCE) TISSUE AUGMENTATION CONSENT**

**D. Benefits**

Radiesse has been shown to be safe and effective when compared to collagen skin implants and related products for treatment of the skin on the face. Radiesse works by stimulating the body to build its own collagen in the matrix of gel that carries the calcium hydroxylapatite crystals. This augmentation can last for extended periods and some clients report satisfaction with the cosmetic result for periods of up to two years.

**E. Alternatives**

This is a strictly voluntary cosmetic procedure. No treatment is necessary or required. Alternative treatments which vary in sensitivity, effect and duration include: animal-derived collagen filler products, dermal fillers derived from one's own fat, synthetic permanent implants, calcium crystal based fillers, and for some wrinkles, injections of bacteria derived toxins.

**F. Questions**

By signing below, you certify that this procedure has been explained to you to your satisfaction. Any further questions can be directed directly to CoZmedic Surgery Associates and its physicians.

**G. Consent**

I have reviewed this consent form. My consent and authorization for this procedure are strictly voluntary. By signing this informed consent form I grant authority for Dr. \_\_\_\_\_ or his/her designee to perform the described procedure and/or administer any related treatment as deemed necessary or advisable for my medical condition.

The purpose of this procedure, risks, complications and alternative methods of treatment have been fully explained to my satisfaction. I understand the distinction between "on-label" and "off-label" use of Radiesse. No guarantee has been given by anyone as to the results that may be obtained by this treatment.

I have read this informed consent and certify that I understand its contents in full. I have had enough time to consider the information and feel that I am sufficiently advised to consent to this procedure. I hereby give my consent to have this procedure.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_

---

PLACE PRODUCT INFORMATION STICKERS HERE: