



THE MENKES CLINIC

Medical, Surgical and Cosmetic Dermatology

RADIESSE CONSENT FORM

Radiesse (formerly known as Radiance FN) is a relatively new injectable product used in a variety of applications. Its primary advantage is its potential for long-lasting effect, and its moldable nature.

Radiesse consists of calcium hydroxylapatite microspheres suspended in a gel carrier, made up of water, glycerin, and carboxymethylcellulose. All of this product's components are on the FDA's G.R.A.S. (Generally Regarded as Safe) list due to their decades-long safe use in other products. Calcium hydroxylapatite is a mineral component of bone and has been used in the repair of both hard and soft tissue for many years. The gel carrier's components have been safely used as food additives. Since Radiesse doesn't elicit a chronic inflammatory or immune response it does not require allergy testing.

The longest term studies of Radiesse, which have been performed in Italy, suggest this is a promising agent for facial contouring with no serious side effects and reasonable efficacy and durability.

Although this product is FDA-approved for other applications, such as for soft tissue augmentation (injected into the vocal cord) and for maxillofacial reconstruction, it is not yet approved for aesthetic indications. Use of this product is considered "off-label" and is thereby used at the discretion and judgement allowed by the FDA to physicians. Long-term studies are currently ongoing, and FDA approval is expected.

PATIENT ACKNOWLEDGEMENT OF RECEIPT OF INFORMATION

Patients Name _____

Date _____

California law requires that your physician obtain your informed consent to medical treatment. In keeping with the California state law, you are being asked to sign a confirmation that we have discussed the nature of your condition, your contemplated medical procedure, the general nature of the proposed treatment, the request of the proposed treatment, the prospects for success, the reasonable therapeutic alternatives to the treatment, and the risks of such alternatives. Your physician has discussed with you the common problems or risks. We wish to inform you as completely as possible. You are also being asked to sign a confirmation that you have been given the opportunity to ask whatever questions you had and that your questions have been answered in a satisfactory manner. Please read the form carefully. Ask about everything you do not understand and we will be pleased to explain it.

Radiesse[™]

I hereby authorize and direct Dr. Menkes to inject me with Radiesse.

Injection of Radiesse into lips, facial folds or lines, depressed scars, or other areas of cosmetic correction is not yet FDA-approved. Use of this product is considered "off-label" and is thereby used at the discretion and judgement allowed by the FDA to physicians.

This procedure has been explained to me. Alternative methods have also been explained to me, as have the advantages and disadvantages. The risks of not being treated have also been explained to me. I am advised that, although good results are expected, the possibility and nature of complications cannot be accurately anticipated and that, therefore, there can be no guarantee as expressed or implied either as to the success or other results of the treatment.

Alternatives to this procedure and the associated risk are to not have the injection of Radiesse.

Risks of having this procedure are:

- 1) Poor cosmetic result, extrusion, disfigurement, infection, asymmetry, swelling, redness, bruising, nodule formation, firm or hard areas on lips, folds or lines, inadequate correction of areas injected. Radiesse is not a permanent implant, and as such resorption of the implant will occur.
- 2) This is not yet FDA-approved for lip augmentation or correction of depressions and lines. The long-term effects on the body are unknown.

These risks have been explained to me including the risks known to be associated with the procedure as required by the California Medical Disclosure Panel.

I hereby state that I have read (or it has been read to me) and I understand this consent and the information contained within. I have had the opportunity to ask any questions about the treatment including risks or alternatives, and I acknowledge that all of my questions about this procedure have been answered in a satisfactory manner.

Signature of Patient

Date

Witness

Date