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INFORMED CONSENT for Radiesse FACIAL ENHANCEMENT

This form is designed to educate you about a new, long lasting tissue filler that is already FDA approved for injection into other areas of the body and is being used "off-label" for filling facial wrinkles, depressed acne scars and defining lips. Like all elective cosmetic procedures, **Radiesse™** injections can have benefits and risks that you should be aware of, but not be frightened by. After you have discussed the nature of your condition, your contemplated medical procedure, prospects for success, risks and reasonable therapeutic alternatives, (including no treatment at this time), any questions you have should be answered to your satisfaction before you sign this form and consent to the injection of **Radiesse™**.

Radiesse™ is synthetic filler made of micro spheres of calcium hydroxyapatite in an aqueous (water-based) gel. Calcium is an element that is in all living animals. Therefore, there is little risk of inflammation or allergic reactions or side effects from the injection of this substance into tissue. Hydroxyapatite has been used medically for more than 25 years for stabilizing prosthetic implants. When small amounts of **Radiesse™** are injected deep into the skin or superficial soft tissue, the creamy texture of the material feels pliable and natural. The material has been shown to be fairly stable in the body for years. It is gradually replaced by the body's own tissue as it slowly dissolves away over years.

Radiesse™ is currently FDA approved for soft tissue "marking" (shows up on X-ray), anywhere on the body, vocal cord injection and oral/maxillofacial augmentation. FDA approval for facial implantation is pending, but has been done "off-label" without problems for many patients worldwide.

Radiesse™ is injected through a short, fine needle after a small amount of topical anesthetic and/or local anesthetic are used to make the injection of the filler more comfortable. (Please inform us if you have any allergy or side effects from the injection of lidocaine anesthesia, like the dentist uses. **Radiesse™** is carefully injected into the lower part of, or just under the skin. It reduces folds and creases and restores fullness immediately. Minor swelling from the injections typically resolves in about a day. Superficial bruising may occur if you have taken anything that "thins" the blood: Aspirin, Vitamin E, Fish or Flax Seed Oil, Ginkgo, Garlic, St. John's Wart and large doses of Advil or similar drugs. You may return to normal activities immediately after your treatment. You may apply makeup the day following the treatment. You should plan to ice the treatment areas intermittently for the first 24 hours after injection. **Radiesse™** does NOT paralyze or act on the facial muscles or nerves like BOTOX™.

Risks to **Radiesse™** injections include: swelling (usually temporary), bruising, firm/hard areas that resolve over several weeks with massage, and possibility of nodules, (which can form with ANY filler). If you have a history of Herpes re-activation of herpes on or around your lips or (very rarely) allergic reaction are also risks. Additional correction or any complications could necessitate additional treatment(s) at additional cost.

Further, **Radiesse™** should not be considered "permanent", although it is known to last from 1 to 2 years when injected into other areas of the human body. However, it SHOULD be "touched-up" or further augmented 6 to 8 weeks after your first treatment. Since the injected material is long lasting, it is more important to under-correct than over-correct.

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Please initial next to each section to signify your understanding and agreement.

_____ I have had the procedure and risks explained to me and had any questions answered to my satisfaction. I also appreciate the differences, advantages and disadvantages of Radiesse™ injections compared to alternative methods of facial rejuvenation.

_____ I have read this consent and had an opportunity to have any questions answered to my satisfaction.

_____ Digital pictures will be obtained before and after your treatment in order to assess the success of the treatment and will be part of your permanent, private medical file. You may be asked for permission to use these images for education and advertising. If any pictures are used, you will not be identified and any identifying anatomy, skin markings, etc., will be masked or cropped.

_____ I am advised that although good results are expected, medicine is not an exact science and the possibility and nature of complications cannot be anticipated. Therefore, no guarantees can be made as to the success or results of this treatment.

_____ I understand that, while this product is FDA approved for certain uses in the human body, facial injection of **Radiesse™** is an "off-label", until the pending request for this use achieves FDA approval pending 2006.

_____ I hereby authorize Thomas P. McHugh, MD to apply and/or inject anesthesia prior to and during the procedure.

_____ I further authorize Thomas P. McHugh, MD to then inject **Radiesse™** into my facial tissues for the correction and aesthetic improvement of wrinkles that are present when my face is at rest, depressed scars and pox marks and/or to improve the definition of my lips.

_____ It is my responsibility to update the office with current addresses and phone numbers and keep follow-up appointments as scheduled during the duration of the treatment or Dr. McHugh will not be responsible, in any way, for my results.

This consent is valid until all or part of it is revoked by me in writing.

Signature of Patient or Person Authorized to Sign

Date

Original signed form to chart. Copy to patient.