**Pelosi Medical Center**

# RADIESSE
## AUTHORIZATION AND CONSENT

Patient Name: _____

Birthdate: ____/_____/____ MR #: _____

## INSTRUCTIONS
This consent form is designed to give you the information you need to make an informed decision about whether or not to undergo treatment with the dermal filler Radiesse. If you have any questions, please ask the clinician at the Center.

## INTRODUCTION
Radiesse treatments involve injections that are planted intradermally through a fine gauge needle into the treated area. Radiesse is comprised of calcium hydroxylapatite (CaHA) microspheres. Multiple treatments may be necessary to achieve desired results. Treatments generally last 9-12 months. Touch up treatments may be necessary to maintain desired results.

## ALTERNATIVE TREATMENT
Alternatives to Radiesse treatments include, but are not limited to, other dermal fillers (e.g. collagen, fat, synthetic polymers), laser resurfacing, surgical facelift, lasers for skin laxity, or no treatment at all.

## PATIENTS THAT MAY NOT BE ELIGIBLE FOR RADIESSE TREATMENTS
Patients with the following conditions may not receive Radiesse treatments: previous allergic reactions to injectable products, history of a serious allergic reaction (anaphylactic), multiple severe allergies, abnormal raised scarring or keloid formation, active inflammation or infection in the treatment area (e.g. pimples, rash, hives), pregnancy, or nursing.

Certain conditions require caution with injectable fillers and may preclude a patient from receiving the treatment: poor healing (due to diabetes or other conditions), long-term use of Prednisone or other steroid therapy. Recurrent viral infections such as herpes simplex (cold sores) may be activated by Radiesse treatments. The physician or registered nurse must be notified of these conditions prior to treatments.

## RISKS
The possible risks, side effects, and complications with Radiesse injectable include, but are not limited to:

1. Pain and tenderness during and after treatments at/around the treated site which typically resolves within a few days to a week.
2. Redness and swelling at/around the injection site is common. Itchiness may also occur. These reactions are generally present immediately after treatment and lessen or disappear within a few days to 1 week. Some patients may experience prolonged swelling and/or tenderness/pain at the injection site lasting up to 2 weeks. Some patients may experience a delayed onset of these symptoms up to several weeks after treatment. On rare occasions, pustules (acne-like lesions) may form. The physician must be notified if symptoms persist for more than 1 week, pustules are present, or symptoms appear in a delayed fashion after treatment.
3. Bruising which usually resolves within 1-2 weeks after the injection. Patients taking medications that interfere with coagulation (e.g. aspirin, ibuprofen) have an increased risk of bruising and bleeding.
4. Infection at the treated site.
5. Although rare, local tissue damage can occur with skin breakdown, scab formation, and/or scarring in the treated area.
6. Visible raised areas and lumpiness at/around the treated site grayish discoloration of the skin. These symptoms may persist from a few weeks to several months and may be permanent (rarely).
7. Failure to reduce a contour defect or wrinkle (under correction) or overcorrection. Placement of filler adjacent to or outside the desired treatment area; undesired changes in facial contour. Asymmetry, where the correction on one side may be different from the correction on the other side of the face. Swelling at time of injection may create the appearance of asymmetry or under correction which usually resolves as described above. However, you may need to return for additional treatment if under correction of asymmetry persists.
8. Radiesse injectable may have an unpredictable duration of action and may not last as long as anticipated or may persist in some areas longer than anticipated.
9. All the risks of Radiesse injectable use may not be known. Pelosi Medical Centeris not responsible for any Radiesse injectable risk or unforeseen complication not yet discovered or not commonly known.

## DISCLAIMER
Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your physician may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are



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determined on the basis of all the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

## INFORMED CONSENT – RADIESSE INJECTABLE

_____ I consent to administration of any related treatments that may be deemed necessary or advisable for my procedure. This includes, but is not limited to, local anesthetic such as anesthetic injections with lidocaine 1%-2% with or without epinephrine; and/or topical anesthetics such as benzocaine/lidocaine/tetracaine cream or ointment; and/or topical oral benzocaine preparations. The risks, side effects, complications of these anesthetics include, but are not limited to, skin irritation (itching or redness), lightheadedness, rapid heart rate, visual disturbances, and tongue numbness. I will inform the physician or registered nurse immediately if I experience any of these symptoms. I do not have an allergy to lidocaine or anesthetics.

_____ No guarantees can be made or have been made that I will benefit from treatment or achieve a desired level of correction. There is no guarantee that wrinkles or folds will be reduced. I understand that I may require additional treatments to achieve correction.

_____ I understand that the fees for Radiesse injectable treatments are not covered by insurance. Should I require a touch-up treatment, I am responsible for the cost of that additional treatment.

_____ I understand that Radiesse will not correct the underlying cause of facial fat loss but will improve the appearance in the treated area.

_____ Microspheres in Radiesse can be seen on X-Rays & CT Scans. I understand I must inform my doctor and other health professionals that I have received Radiesse injections.

_____ If I take any blood thinners such as ibuprofen, aspirin, or herbal preparations prior to my procedure, I will advise my physician, registered nurse, physician assistant, or nurse practitioner. I understand that use of these medications may increase my risk of bruising.

_____ Possible side effects can include but are not limited to: Allergic reaction or infection. Bleeding, tenderness or pain, redness, bruising, scarring, Keloid formation/hypertrophic scarring or swelling at injection site.

_____ I understand if I have a history of Keloid formation or hypertrophic scarring, I must advise my physician and I am aware that will not be eligible for this treatment.

_____ I have fully read and agree to adhere to pre-treatment and post treatment instructions. I understand that failure to carefully follow these instructions may affect my treatment outcome and increase the likelihood or severity of complications.

_____ I consent to photography; these photos will be kept confidential and will become part of my medical record with Pelosi Medical Center.

_____ I have fully disclosed all of my medical history. I understand that it is my responsibility to inform and update the physician or registered nurse of any change in my health status and medical history.

_____ I am an adult of at least 18 years of age. My signature below certifies that I have fully read this consent form and understand the information provided to me regarding the proposed procedure. I have been adequately informed about the procedure involving the potential benefits, limitations, alternative treatments. I have had enough time to consider the information, and I have had all questions and concerns answered to my satisfaction. I understand and accept the risks, side effects, and possible complications associated with Radiesse injectable treatment.

_____ I consent and authorize a trained physician, registered nurse, physician assistant, or nurse practitioner of Pelosi Medical Center to perform Radiesse injectable treatments. This consent shall apply to all Hyaluronic acid treatments.

_____ If I have any questions or problems after treatment, I will call Pelosi Medical Center immediately.

_____ It has been explained to me in a way that I understand:

A. The above treatment or procedure to be undertaken
B. There may be alternative procedures or methods of treatment
C. There are risks to the procedure or treatment proposed

**I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-10) AND I AM SATISFIED WITH THE EXPLANATION.**

| _____ | ___/___/___ | _____ | ____/___/____ |
|---|---|---|---|
| Patient Signature | Date | Physician Signature | Date |