**ITHACA MEDICAL AESTHETICS**

Refresh \* Restore \* Rejuvenate

**Dana Gabriela Negoi, Physician, PLLC 107 N. Cayuga St., Ste 7 (607) 603-7002**

**INFORMATION SHEET AND INFORMED CONSENT**

**Radiesse**® **FACIAL FILLER INJECTION**

**TREATMENT**

Radiesse® dermal filler consists of tiny, smooth, calcium hydroxylapatite (CaHA) microspheres suspended in a sodium carboxymethylcellulose gel carrier. Upon injection, it initially acts as a filler. It is easily malleable, can be used to shape and contour large areas of the face, and provides an immediate one-to-one correction for results patients can see right away. Once injected, Radiesse® dermal filler starts the process we refer to as neocollagenesis, stimulating the steady, ongoing growth of the body’s own collagen. In fact for many patients, the benefits of treatment with Radiesse® dermal filler last up to a year or more. 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 in HIV patients. It is important that you read this information carefully and completely.

Fillers cannot stop the process of aging. They can however, temporarily diminish the look of wrinkles and soft tissue depressions. Filler injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. Once injected, fillers will be slowly absorbed by the body. The length of effect for injections is variable.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. 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.

Filler injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. Filler injections may require regional nerve blocks or local anesthetic injections to diminish discomfort.

**ALTERNATIVE TREATMENTS:** Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments such as: laser treatments, chemical skin-peels, dermabrasion, or other skin procedures, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are also associated with alternative forms of medical or surgical treatment.

**RISKS OF FILLER INJECTIONS:** Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual’s choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of facial filler injections. Additional information concerning Radiesse®may be obtained from the package-insert supplied by Merz Aesthetics. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with facial filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. 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.

**Pain, Swelling and Redness:** Swelling is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary. Discomfort associated with injections is normal and usually of short duration. Redness may occur after injection and be present for a few days.

**Needle Marks:** Visible needle marks from the injections occur normally and resolve in a few days.

**Skin Sensitivity:** Skin rash, itching, and tenderness may occur following injections. After treatment, you should minimize exposure to excessive sun or UV lamp exposure and extreme heat for 24 hours after treatment. If you are considering laser treatment, chemical skin peeling or any other procedures after injection or you have recently had such treatment, there is a possible risk of an inflammatory reaction at the injection site.

**Infection:** Although infection following injection of filler is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virusinfections (“Herpes”) around the mouth can occur following injection near the mouth in individuals with a past history of Herpes and individuals with no known history of Herpes in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus.

**Under / Over Correction:** The injection of soft tissue fillers to correct wrinkles and soft tissue contour deficiencies may not achieve the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of tissue fillers due to factors attributable to each patient’s situation. If under correction occurs, you may be advised to consider additional injections of tissue filler materials. **Asymmetry:** The human face is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filer injections. There can be a variation from one side to the other in terms of the response to injection. Addressing this may require additional injections to the same or nearby areas. However, in some cases this uneven appearance can persist for several weeks or months.

**Accidental Intra-Arterial Injection**: It is extremely rare that during the course of injection, fillers could be accidentally injected into arterial structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the eye, resulting in loss of vision or vision abnormalities. These complications can also include stroke, temporary scabs, or permanent scarring of the skin. If you have changes in your vision, signs of a stroke (including sudden difficulty speaking. numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin or unusual pain during or shortly after treatment, you should notify your healthcare practitioner immediately. The risk and consequences of accidental intravascular injection of fillers is unknown and not predictable. Deeper structures such as nerves and blood vessels may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent and cause unacceptable scarring.

**Skin Lumpiness:** Lumpiness can occur following the injection of fillers. This tends to smooth out over time. In some situations, it may be possible to feel the injected tissue filler material for long periods of time. It may also be possible to see tissue filler material that was injected in areas where the skin is thin. **Granulomas:** Painful masses in the skin and deeper tissues after a filler injection are extremely rare. Should these occur, additional treatments including surgery may be necessary. Fillers should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives). **Migration of Filler:** The filler substance may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

**Allergic Reactions and Hypersensitivity:** As with all biologic products, allergic and systemic anaphylactic reactions may occur. Fillers should not be used in patients with a history of multiple severe allergies, severe allergies manifested by a history of anaphylaxis, or allergies to gram-positive bacterial proteins. There is the possibility that a systemic reaction could occur from either the local anesthetic used for sensory nerve block anesthesia when tissue filler injections are performed. This would include the possibility of light-headedness, rapid heartbeat (tachycardia), and fainting. Medical treatment of these conditions may be necessary. It is not known if Radiesse® reacts with other drugs within the body.

**Antibodies to Fillers:** Presence of antibodies to hyaluronic acid tissue fillers may reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to hyaluronic acid tissue fillers and other fillers is unknown.

**Unsatisfactory Result:** Filler injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response from filler injection(s). Additional injections may be necessary. Surgical procedures or other treatments may be recommended in addition to additional treatments.

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

**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(s). 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 medical provider may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the current 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 determined on the basis of all of 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 FOR RADIESSE® TREATMENT**

1. I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,have read the 2 page information sheet and hereby authorize my medical provider and/or such assistants as may be selected to perform the **Radiesse®** treatment.
2. I understand what my medical provider can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
3. I understand that multiple treatments are necessary to achieve desired results. Treatments generally last from 4 to 6 months. Touch up treatments may be necessary to maintain desired results. No guarantee, warranty, or assurance has been made to me as to the results that may be obtained. Clinical results will vary per patient. I agree to adhere to all safety precautions and regulations during the treatment.
4. I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost of collection, and /or court cost and reasonable legal fees, should this be required. No refunds will be given for treatments received.
5. I have read and understand the Pre and Post-Treatment Instructions. I agree to follow these instructions carefully. I understand that compliance with recommended pre and post procedure guidelines are crucial for healing, prevention of side effects and complications as listed above.
6. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
7. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
8. I acknowledge that I have been informed that some of the treatment may be “Off-label”. I understand that it is not experimental and accept its use.
9. I understand that I can withdraw my consent at any time.

**Print Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Patient Signature/Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Witness Signature /Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**