DALLAS
PLASTIC SURGERY
INSTITUTE

Patient Name: _____

Date: _____

RADIESSE AND/OR SCULPTRA INFORMED CONSENT

Product:

☐ RADIESSE ☐ SCULPTRA

This is an informed consent document which has been prepared to help your plastic surgeon inform you concerning Radiesse and Sculptra injections and its risks.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page, and sign the consent for this procedure as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

Radiesse is filler used to smooth moderate to severe facial wrinkles and folds around the nose and mouth or shape facial contours. **Radiesse** is popular especially for filling the nasolabial folds - the creases that extend from the corner to your nose to the corner of your mouth. **Radiesse** has been FDA approved for the cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions.

Radiesse consists of calcium hydroxylapatite which is a biocompatible (compatible with living systems), biodegradable (dissolves in the body) material. Calcium hydroxylapatite is identical in composition to the mineral portion of teeth and bone. **Radiesse** is synthetically produced containing micro spheres made of a natural material called calcium hydroxylapatite in a water-based gel carrier.

Radiesse injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the face. **Radiesse** cannot stop the process of aging. It can, however, temporarily diminish the look of wrinkles and soft tissue depressions. **Radiesse** injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. **Radiesse** injections require regional nerve blocks or local anesthetic injections to diminish discomfort. Soft tissue fillers produce temporary swelling, redness, and needle marks, which resolve after a few days time. Continuing treatments may be necessary in order to maintain the effect of **Radiesse** over time. **Radiesse** once injected will be slowly absorbed by the body. The length of effect for **Radiesse** injections is variable, in a clinical study it was reported to last 6 months.

Sculptra® Aesthetic is an FDA approved injectable poly-L-lactic acid implant in a sterile form of apyrogenic suspension. Poly-L-lactic acid is a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxyacid family. Poly-L-lactic acid has been used medically for many years in dissolvable sutures and does not require pre-treatment skin testing for allergies.

Sculptra® Aesthetic is injected into the skin and underlying tissues. It is designed to help correct skin depressions, such as wrinkles, folds, scars, degenerative skin, aging, and facial lipoatrophy.

Depending upon the area and condition treated, patient factors, the volume of **Sculptra®** Aesthetic used, and the injection technique, the effect of a treatment with **Sculptra®** Aesthetic may last from 1 to 2 years but the duration of the effect can be shorter or longer. Most areas of treatment will require 2 to 4 session, usually at 4 to 6 week intervals, for optimal correction. Because individual responses to **Sculptra®** Aesthetic therapy may vary, the exact number of treatment sessions required cannot be predicted with complete accuracy. In addition, to maintain the desired degree of correction, intermittent "touch-up" treatments may be needed. After each injection session,

tissue volume in the treated area will gradually build up over the following weeks and months as the body produces new collagen.

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: 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 associated with alternative forms of medical or surgical treatment.

RISKS OF RADIESSE AND OR SCULPTRA 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 a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand risks, potential complications, limitations, and consequences of hyaluronic acid injections. Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections.

Risks include but are not limited to: Bleeding and Bruising, swelling, erythema, needle marks, acne-like skin eruptions, skin lumpiness, visible tissue filler material, asymmetry, pain, complications, infections, damage to deeper structures, skin necrosis, granulomas, allergic reactions and hypersensitivity, micron-nodules, accidental intra-arterial injection leading to tissue necrosis and possible blindness, skin hypertrophy, under/over correction, drug and local anesthetic reactions, unsatisfactory result, unknown risks, migration, drug and local anesthetic reactions, combination procedures, complications to pregnancy or nursing, drug interactions, or long term effects.

OFF-LABEL FDA USE

There are many devices, medications, injectable fillers, and botulinum toxins that are approved for specific use by the FDA, but this proposed use is "Off-Label", that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your physician believe it to be safe and effective. Examples of commonly accepted "Off-Label" use of drugs or devices include the use of aspirin for prevention of heart disease, retinoids for skin care, and injection of botulinum toxin for wrinkles around the eyes.

____ I acknowledge that I have been informed about the Off-Label FDA status of _____ and I understand it is experimental and accept its use.

ADDITIONAL TREATMENT NECESSARY

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of facial filler injections. 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 and surgery 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.

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DISCLAIMER

Informed consent documents are used to communicate information about the proposed surgical 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 plastic surgeon 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 YOUR QUESTIONS ANSWERED BEFORE SIGNING THE CONSENT ON THE NEXT PAGE

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Patient Name: _____

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INFORMED CONSENT FOR RADIESSE AND OR SCULPTRA INJECTIONS

1. I hereby authorize Dr. Rohrich and such assistants as may be selected to perform the following procedure or treatment**: Radiesse and or Sculptra Injections**
2. I recognize that during the course of the procedure and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
4. 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.
5. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
6. 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. I AM SATISFIED WITH THE EXPLANATION.

Treatment Date _____

Patient Name _____ Patient Signature _____

Witness Name _____ Witness Signature_____

_____

Treatment Date _____

Patient Name _____ Patient Signature _____

Witness Name _____ Witness Signature_____

_____

Treatment Date _____

Patient Name _____ Patient Signature _____

Witness Name _____ Witness Signature_____