Dep AESTHETICS INSTITUTE
INTEGRATED ADVANCEMENTS

RADIESSE® Informed Consent

RADIESSE® injectable implant is indicated for subdermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and it is also intended for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus.

As a patient, you have the right to be informed about your treatment so that you may make the decision whether to proceed with, or decline treatment(s) with RADIESSE® after knowing the risks involved. This disclosure is to help inform you prior to your consent for treatment about the possible risks, side effects, and complications related to treatment with

Patients should not receive treatment with RADIESSE® if any of the following are true:

- Severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies.
- Known hypersensitivity to any of the components.
- Active skin inflammation or infection in or near the treatment area (should be deferred until the inflammatory or infectious process has been controlled)
- Pregnancy or nursing
- Under 18 years of age

Patients with a history of cold sores may experience a recurrence after the treatment, although this can be minimized by the use of antiviral medicines. Inform your nurse or doctor if you have a history of cold sores.

Precautions and the possible risks of treatment with RADIESSE® may include but are not limited to the following:

- Common short term risks include bleeding, tenderness, pain, redness and bruising.
- Infection at site
- Over correction
- Granuloma formations
- Allergic reaction
- Keloid formation/hypertrophic scarring at injection site
- Injection into blood vessel may occlude the vessels and could cause infarction or embolism leading to ischemia, necrosis or scarring. This has been reported to occur in the lips, nose, glabellar or ocular area.

The calcium hydroxylapatite (CaHA) particles of RADIESSE® injectable implant are radiopaque and are clearly visible on CT Scans and may be visible in standard, plain radiography. Patients need to be informed of the radiopaque nature of RADIESSE® injectable implant, so that they can inform their primary care health professionals as well as radiologists. In a radiographic study of 58 patients, there was no indication of RADIESSE® injectable implant potentially masking abnormal tissues or being interpreted as tumors in CT Scans.

Safety of RADIESSE injectable implant beyond 3 years has not been investigated in clinical trials. Safety and effectiveness in the periorbital area has not been established.

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Client Initials

The safety of RADIESSE injectable implant in patients with increased susceptibility to keloid formation and hypertrophic scarring has not been studied.
Safety of RADIESSE® injectable implant for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established.

Patients who are using medications that can prolong bleeding, such as aspirin or warfarin, fish oil, vitamin E, may, as with any injection, experience increased bruising or bleeding at the injection site.

Exposure of the treated area to extensive sun or heat exposure should be minimized for approximately 24 hours after treatment or until any initial swelling and redness has resolved.

No studies of interactions of RADIESSE® injectable implant with drugs or other substances or implants have been conducted.

The safety of RADIESSE® injectable implant with concomitant dermal therapies such as epilation, UV irradiation, or laser, mechanical or chemical peeling procedures has not been evaluated in controlled clinical trials.

Call your doctor if you have any side effect that bothers you or does not go away.

I understand that multiple treatments may be necessary to achieve desired results. Touch up treatments may be necessary to maintain desire results. Clinical results may vary depending on individual factors, including medical history, patient compliance with pre/post treatment instructions, and individual response to treatment. I understand that RADIESSE® will not correct the underlying cause of facial volume loss but may improve the appearance of the treated area. No guarantee, warranty or assurance has been made to me as to the results that may be obtained with RADIESSE®.

By signing below, I certify that I have read and fully understand the contents of this document and that I have received and understand all of the disclosures referred herein. I certify that I have none of the listed contraindications and I have been given the opportunity to ask questions regarding the procedure. All of my questions have been answered to my satisfaction and I fully accept the risks of the proposed procedure. I freely consent to the proposed treatment and hereby release authorized
DEP Aesthetics Institute™ staff from all liabilities associated with RADIESSE®.

Client Signature _____ Date _____

Client Printed Name _____

DEP Aesthetics Institute™ Representative Signature _____