

INFORMED CONSENT– DERMAL FILLER INJECTION

This is an informed consent document which has been prepared to help inform you concerning Hyaluronic Acid Filler such as Restylane®, Juvaderm, & Belotero. (Non-Animal Stabilized Hyaluronic Acid) tissue filler injection therapy, its risks, and alternative treatments. As well as Radiesse, a sterile, latex-free, non-pyrogenic, semi-solid, cohesive subdermal, injectable implant, whose principal component is synthetic calcium hydroxylapatite, a biocompatible material with over 20 years of use in medicine, approved for use in hands, cheeks, and pre-jowl sulcus. Hyaluronic acid is a naturally occurring substance that is found within all mammals. It is a material that is contained in various soft tissues. Hyaluronic acid can be synthetically produced from a process of bacterial fermentation, chemically stabilized, and purified for use as an injectable soft tissue filler (non-animal, stabilized hyaluronic acid). The hyaluronic acid in Dermal-Fillers is biocompatible and is a totally non-animal product; there is little risk of animal-based disease transmission or allergic reaction. Dermal-fillers can be performed in areas involving the face, eyebrows, temples, undereyes, nose, jaw, chin, jowels, cheeks, hands, forehead, and lips, just to name a few and some areas are considered Off-Label use, not FDA approved areas. Dermal-Filler injections contain local anesthetic in the syringe to diminish discomfort. Continuing treatments are necessary in order to maintain the effect of Fillers over time, they do not stop the aging process. Once injected, dermal-fillers will be slowly absorbed by the body. The length of effect for fillers injections is variable and depends on the person.

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, other skin procedures, or alternative types of tissue fillers.

RISKS OF FILLER INJECTIONS

An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit.

Normal Occurrences during Tissue Filler Injections include:

Bleeding and Swelling - Swelling (edema) is a normal occurrence following the injections. It decreases after a few days or weeks.

Erythema (Skin Redness) - Erythema in the skin occurs after injections. It can be present for a few days after the procedure.

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

Acne-Like Skin Eruptions - skin eruptions can occur following the injection of tissue fillers that generally resolve within a few days.

Skin Lumpiness - Lumpiness can be treated with hyaluronidase to smooth it out if necessary.

Visible Tissue Filler Material - This can be resolved with hyaluronidase

Asymmetry - It may not be possible to achieve or maintain exact symmetry with tissue filler injections.

Pain - Discomfort associated with injections is normal and usually of short duration.

RISKS OF DERMAL-FILLER INJECTIONS

Damage to Deeper Structures - 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.

Infection – unusual, herpes outbreaks can be triggered

Skin Necrosis - It is very unusual to experience death of skin and deeper soft tissues after dermal-filler injections. Skin necrosis can produce unacceptable scarring. Should this complication occur, additional treatments, or surgery may be necessary.

Allergic Reactions and Hypersensitivity

Scarring - Dermal-fillers maybe susceptible to keloid formation or hypertrophic scarring.

Granulomas - Painful masses in the skin and deeper tissues after a dermal-filler injection are extremely rare. Should these occur, additional treatments including surgery may be necessary.

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 is unknown.

Accidental Intra-Arterial Injection - It is extremely rare and unpredictable

Under /Over Correction - 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. If over correction occurs, the use of hyaluronidase can decrease the volume.

Migration of Dermal-Fillers - Dermal-fillers may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

Drug and Local Anesthetic Reactions - There is the possibility that a systemic reaction could occur from the local anesthetic when tissue filler injections are performed. This would include the possibility of light-headedness, numbness, and, allergic reaction, and fainting. Medical treatment of these conditions may be necessary.

Unsatisfactory Result - Dermal-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).

Pregnancy and Nursing Mothers - Animal reproduction studies have not been performed to determine if dermal-filler could produce fetal harm. It is not known if Restylane®, Juvaderm, or Belotero or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive dermal-filler treatments.

Drug Interactions - It is not known if fillers reacts with other drugs within the body.

Label FDA Issues

There are many devices, medications and injectable fillers that are approved for specific use by the FDA, but some 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 believes it to be safe and effective.

____ I acknowledge that I have been informed about the Off-Label FDA status & uses of dermal-fillers such as Juvaderm, Restylane, & Belotero and I understand it is not experimental and accept its use.

FINANCIAL RESPONSIBILITIES

I understand and agree that all services rendered to me are charged to me directly and that I am personally responsible for payment. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome.

Additional costs may occur should complications develop from the injections and will also be your responsibility. In signing the consent for this procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

____ I understand and unconditionally and irrevocably accept this & that all costs are NON-REFUNDABLE

DISCLAIMER

Informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered.

I hereby authorize **Natural Injections and it’s trained licensed designees** to perform the injection of hyaluronic acid dermal fillers such as Juvaderm, Resylane, or Belotero

1. I have received and read the INFORMED CONSENT and PRE & POST PROCEDURE INSTRUCTIONS that were explained to me & I agree to follow all instructions, to follow up as directed, and to notify the office if any problems or questions arise.
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 mentioned provider to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. The nature and purpose of the treatment have been explained to me. I understand what my provider can and cannot do, and I 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. I have read and understand this agreement. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement. Alternative methods of treatment and their risks and benefits have been explained to me.
5. I understand that I have the right to refuse treatment. By signing this form, I elect to proceed with treatment.
6. I consent to be photographed or televised before, during, and after the 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.

____ I take full liability and responsibility for any and all risks, undesired outcomes, or adverse events associated with the injections and will not hold the providers or Natural Injections liable for any unfavorable outcome or adverse event. I release Natural Injections LLC, owners, and medical staff from liability associated with the procedure. This consent form is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-7). I AM SATISFIED WITH THE EXPLANATION.

Patient Signature

Date _____

Patient Printed Name: _____

Witness: _____