

INFORMED CONSENT FOR DERMAL FILLER TREATMENT

ADVANCED SKIN & VEIN CARE CENTERS

PATIENT _____

DATE OF BIRTH _____

ADDRESS _____

PHONE _____

The purpose of this informed consent form is to provide written information regarding the risks, benefits and alternatives of the procedure named above. This material serves as a supplement to the discussion you have with your doctor/healthcare provider. It is important that you fully understand this information, so please read this document thoroughly. If you have any questions regarding the procedure, ask your doctor/healthcare professional prior to signing the consent form.

THE TREATMENT

Treatment with dermal fillers (such as Juvederm, Restylane, Radiesse, Voluma, Radiesse, Boletero and others) can smooth out facial folds and wrinkles, add volume to the lips, and contour facial features that have lost their volume and fullness due to aging, sun exposure, illness, etc. Facial rejuvenation can be carried out with minimal complications. These dermal fillers are injected under the skin with a very fine needle. This produces natural appearing volume under wrinkles and folds which are lifted up and smoothed out. The results can often be seen immediately. **Initial** _____

RISKS AND COMPLICATIONS

Before undergoing this procedure, understanding the risks is essential. No procedure is completely risk-free. The following risks may occur, but there may be unforeseen risks and risks that are not included on this list. Some of these risks, if they occur, may necessitate hospitalization, and/or extended outpatient therapy to permit adequate treatment. It has been explained to me that there are certain inherent and potential risks and side effects in any invasive procedure and in this specific instance such risks include but are not limited to:

Normal Occurrences during Tissue Filler Injections

Bleeding and Bruising: It is possible, though unusual, to have a bleeding episode from a filler injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba and other "herbs / homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before or after filler injections.

Swelling: Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

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

Specific Risks of Filler Injections

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

Acne-Like Skin Eruptions: Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.

Skin Sensitivity: Skin rash, itching, tenderness and swelling may occur following injections. After treatment, you should minimize exposure of the treated area to excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. If you are considering laser treatment, chemical

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skin peeling or any other procedure based on a skin response after filler treatment, or you have recently had such treatments and the skin has not healed completely, there is a possible risk of an inflammatory reaction at the implant site.

Infection: Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth can occur following a tissue filler treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections 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. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

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

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 filler 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.

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.

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.

Visible Tissue Filler Material: It may be possible to see any type of 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.

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

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. Allergic reactions may require additional treatment.

Drug and Local Anesthetic Reactions: There is the possibility that a systemic reaction could occur from either the local anesthetic or epinephrine used for sensory nerve block anesthesia when tissue filler injections are

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performed. This would include the possibility of light-headedness, rapid heartbeat (tachycardia), and fainting. Medical treatment of these conditions 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 and other fillers is unknown.

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. The risk and consequences of accidental intravascular injection of fillers is unknown and not predictable.

Scarring: Fillers should not be used in patients with know susceptibility to keloid formation or hypertrophic scarring. The safety of patients has not been studied.

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. Dermal fillers have been shown to be safe and effective when compared to collagen skin implants and related products to fill in wrinkles, lines and folds in the skin on the face. Its effect can last up to 9-12 months. Most patients are pleased with the results of dermal fillers use. However, like any esthetic procedure, there is no guarantee that you will be completely satisfied. There is no guarantee that wrinkles and folds will disappear completely, or that you will not require additional treatment to achieve the results you seek. The dermal filler procedure is temporary and additional treatments will be required periodically, involving additional injections for the effect to continue. I am aware that follow-up treatments will be needed to maintain the full effects. I am aware the duration of treatment is dependent on many factors including but not limited to: age, sex, tissue conditions, my general health and life style conditions, and sun exposure. I have been instructed in and understand the post-treatment instructions.

Initial _____

PREGNANCY AND ALLERGIES

I am not aware that I am pregnant. I am not trying to get pregnant. I am not lactating (nursing). I do not have or have not had any major illnesses which would prohibit me from receiving dermal fillers. I certify that I do not have multiple allergies or high sensitivity to medications, including but not limited to lidocaine. **Initial** _____

FINANCIAL RESPONSIBILITIES

The cost of filler injection may involve several charges. This includes the professional fee for the injections, follow up visits to monitor the effectiveness of the treatment, and the cost of the filler material itself. It is understood that filler injections to treat cosmetic problems are not covered by your health insurance. 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 surgery/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.

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CONSENT FOR SURGERY/ PROCEDURE or TREATMENT

1. I hereby authorize Dr. Ziad Sara and such assistants as may be selected to perform the following procedure or treatment: FACIAL FILLER INJECTION
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 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. I understand what my physician 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.
5. 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.
6. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
7. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medicaldevice registration, if applicable.
8. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
9. I realize that not having the procedure is an option.
10. 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.

Patient or Person Authorized to Sign for Patient

Date _____ **Witness** _____