



## ACKNOWLEDGEMENT OF ADDITIONAL RISKS ASSOCIATED WITH DERMAL FILLERS

\_\_\_\_\_ 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 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 known 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 product may be necessary. Other treatments may be recommended in the event of adverse outcomes.

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\_\_\_\_\_ Unknown Risks: 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.

\_\_\_\_\_ Combination of Procedures: 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.

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

\_\_\_\_\_ Drug Interactions: It is not known if facial filler reacts with other drugs within the body.

\_\_\_\_\_ Long-Term Effects: \* Hyaluronic Acid Filler or other facial filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. \* Over time, the facial filler material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. \*Continuing facial filler treatment (injections) is necessary in order to maintain the effect of the Filler. \*Subsequent alterations in face and eyelid appearance may occur as a 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. \* Facial Filler injection does not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

### ADDITIONAL ADVISORIES.

\_\_\_\_\_ Mental Health Disorders: Effects on mental health cannot be accurately predicted. It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable.

\_\_\_\_\_ Sun Exposure – Direct or Tanning Salon: The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

\_\_\_\_\_ Medications and Herbal Dietary Supplements: There are potential adverse reactions that occur as a result of taking over-the-counter, herbal, and/or prescription medications that prolong bleeding time: Aspirin and medications that contain aspirin; non-steroidal anti-inflammatories such as Motrin, Advil, and Alleve; Plavix. It is important if you are taking Plavix that you inform your provider. **Stopping Plavix may result in a heart attack, stroke and even death.**

\_\_\_\_\_ Travel Plans & Important Events: There are no guarantees that you will be able to resume all activities in the desired time frame.

\_\_\_\_\_ Off-Label FDA Issues: There are several applications of injectable fillers that are not specifically approved by the FDA. If “off-label” recommendations are made, understand this proposed use *is not* experimental and believed to be safe and effective.

### ADDITIONAL TREATMENT NECESSARY

\_\_\_\_\_ Other complications and risks beyond those cited in this document can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary.

\_\_\_\_\_ 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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