

Informed Consent - Juvéderm™ Restylane® Injection

This is an informed consent document to help inform you concerning Juvéderm™ Restylane® (Non-Animal Stabilized Hyaluronic Acid, *Medicis Aesthetics*) tissue filler injection therapy, its risks and alternative treatments.

It is important that you read carefully and completely. Please initial each page indicating that you read and understood each page.

General Information

Juvéderm™ Restylane® is a stabilized hyaluronic acid used to smooth moderate to severe facial wrinkles and folds around the nose and mouth or shape facial contours. It is approved by the FDA for cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions.

Hyaluronic acid is a naturally occurring substance that is found within all mammals, a material contained in various soft tissues. HA 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, *Medicis Aesthetics*). The HA in Juvéderm™ Restylane® is biocompatible and is a totally non-animal product; there is little risk of animal-based disease transmission or allergic reaction.

Juvéderm™ Restylane® injections are customized per patient, depending on their needs. These can be performed in areas involving the face and eyelid region, forehead, and lips. It cannot, however, stop the process of aging. It can temporarily diminish the look of wrinkles and soft tissue depressions. These injections may be performed as a singular procedure, in combination with other treatments such as Botox®, or as an adjunct to surgical procedure. Juvéderm™ Restylane® injections require regional nerve blocks or local anesthetic injections to diminish discomfort when injected into the lip and lip area. Soft tissue fillers, including Juvéderm™ Restylane® produce temporary swelling, redness and needle marks, which resolve after a few days time.

Continuing treatments are necessary in order to maintain the effect of Juvéderm™ Restylane® over time. Once injected it will be slowly absorbed by the body. The length of effect is variable per individual.

Alternative Treatments

Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, microdermabrasion, 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.

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Risks of Injections

Every procedure involves a certain amount of risk and it is important you understand these and the possible complications associated with them. Every procedure also has limitations. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of Juvéderm™ Restylane® injections. Additional information concerning Juvéderm™ Restylane® may be obtained at www.restylane.com and from the package-insert sheets supplied by Essence of Eve Day Med Spa at your request.

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections, including Juvéderm™ Restylane®. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve Juvéderm™ Restylane®.

Normal Occurrences during Tissue Filler Injections - Juvéderm™ Restylane®

Bleeding & Bruising – possible though unusual. Bruising in soft tissues may occur.

Swelling – Edema is a normal occurrence. It can be present for several days post procedure.

Needle Marks – Occur normally and resolve in a few days.

Acne-Like Skin Eruptions – can occur, generally resolves within a few days.

Skin Lumpiness – can occur, tends to smooth out over time. In some situations may be possible to feel injected tissue filler material for long period of time.

Visible Tissue Filler Material – may be possible to see any type of tissue filler injected in areas where skin is thin.

Asymmetry –The human face is normally asymmetrical in appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with fillers. There can be a variation from one side to the other in terms of response. This may require additional injections.

Pain - discomfort is normal and usually of short duration.

Skin Sensitivity – Skin rash, itching, tenderness and swelling may occur. After treatment you should minimize exposure of 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 skin peeling or any other procedure based on a skin response or if you have had such treatments and the skin has not healed completely, there is a possible risk of an inflammatory reaction in the implant site.

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Risk of Juvéderm™ Restylane® Injections

Damage to Deeper Structures-such as nerves and blood vessels may be damaged. Injury to deeper structures may be temporary or permanent.

Infection – Although 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 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.

Skin Necrosis – 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 & Hypersensitivity – as with all biologic products, allergic and systemic anaphylactic reactions may occur. Juvéderm™ Restylane® 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.

Scarring – Should not be used in patients with susceptibility to keloid formation or hypertrophic scarring. The safety of patients has not been studied.

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

Skin Disorders – Should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives). In rare instances, granuloma or abscess formation, localized necrosis and urticaria have been reported.

Antibodies – to hyaluronic acid tissue fillers may reduce the effectiveness or produce a reaction in subsequent injections. The health significance of antibodies to HA tissue fillers is unknown.

Accidental Intra-Arterial Injection – extremely rare that during the course of injection 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 is unknown and not predictable.

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 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.

Migration – may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

Drug & 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 heart beat (tachycardia) and fainting. Medical treatment of these conditions may be necessary.

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Additional Advisories

Unsatisfactory Results – 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. Additional injections may be necessary. Surgical procedures or other treatments may be recommended in addition to additional dermal filler treatments.

Unknown Risks – long term effect of dermal fillers beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of dermal fillers as a soft tissue filler may be discovered.

Combination of Procedures – In some situations, Botox® injections or other types of tissue filler materials may be used in addition in order to specifically treat areas of the face or to enhance the outcome from tissue filler therapy. 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 dermal fillers is unknown.

Pregnancy & Nursing Mothers – Animal reproduction studies have not been performed to determine if dermal fillers could produce fetal harm. It is not known if their breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing women receive dermal fillers.

Drug Interactions – It is not known if dermal fillers react with other drugs within the body.

Long-Term Effects – dermal fillers should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the filler material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing treatments (injections) is necessary in order to maintain the effect. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to dermal filler injections. Future surgery or other treatments may be necessary. Injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

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.

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.

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It is important that you read the above information carefully and have all of your questions answered before signing the consent below.

Informed Consent

Restylane, Juvederm Ultra, Juvederm Ultra Plus

1. I hereby authorize Dr. Ralph Joseph to perform the following treatment:
Please circle: Restylane Juvederm Ultra Juvederm Ultra Plus
2. I have received the following information sheet, Informed Consent
3. I recognize that during the course of the procedure and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above.
4. 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.
5. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
6. I consent to be photographed before during and after the procedure(s) to be performed, for purpose of being included as a part of record.
7. I realize that not having this procedure is an option.
8. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - A. The above 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 and/or procedure and the above items 1 – 8. I am satisfied with the explanation.

Patient

Date _____ ***Witness*** _____

Dr. Ralph Joseph _____ ***Date*** _____

Internal Use Only:
