



INFORMED CONSENT – RESTYLANE® INJECTION

GENERAL INFORMATION

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. Restylane has been FDA approved for the 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. It is a material that is contained in various soft tissues. Restylane injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips. Restylane cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles and soft tissue depressions. Restylane injections may be performed as a singular procedure, in combination with other injectable treatments. Restylane injections require regional nerve blocks or local anesthetic injections to diminish discomfort. Soft tissue fillers, including Restylane, produce temporary swelling, redness, and needle marks, which resolve after a few days. Continuing treatments are necessary in order to maintain the effect of Restylane over time. Restylane once injected will be slowly absorbed by the body. The length of effect for Restylane injections is variable.

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, dermabrasion, 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.

RISKS OF RESTYLANE® INJECTIONS

Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure 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 Restylane injections. 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 Restylane. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve Restylane.

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Normal Occurrences During Tissue Filler Injections

Bleeding and Bruising: It is possible to have a bleeding episode from a Restylane 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 Restylane 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.
- 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:** Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.
- Skin Lumpiness:** Lumpiness can occur following the injection of Restylane. 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.
- 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 Restylane injection. This may require additional injections.
- Pain:** Discomfort associated with Restylane injections is normal and usually of short duration.

- **Skin Sensitivity:** Skin rash, itching, tenderness and swelling may occur following Restylane 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.

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

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- **Allergic Reactions and Hypersensitivity:** As with all biologic products, allergic and systemic anaphylactic reactions may occur. 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:** Restylane should not be used in patients with known 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 a Restylane injection are extremely rare. Should these occur, additional treatments including surgery may be necessary.
- **Skin Disorders:** Restylane 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 Restylane:** 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 that during the course of injection, Restylane 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 Restylane is unknown and not predictable.
- **Under / Over Correction:** The injection of soft tissue fillers including Restylane 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.
- **Migration of Restylane:** Restylane 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 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.
- **Unsatisfactory Result:** Restylane 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 Restylane injection(s). Additional Restylane injections may be necessary.
- **Unknown Risks:** The long term effect of Restylane beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of Restylane as a soft tissue filler may be discovered.

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- **Pregnancy and Nursing Mothers:** Animal reproduction studies have not been performed to determine if Restylane could produce fetal harm. It is not known if Restylane or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive Restylane treatments.
- **Drug Interactions:** It is not known if Restylane reacts with other drugs within the body.
- **Long-Term Effects:** Restylane injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the Restylane material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing Restylane treatment (injections) is necessary in order to maintain the effect of Restylane. 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 Restylane injections. Future surgery or other treatments may be necessary. Restylane injection does not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

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Off-Label FDA Issues: There are many devices, medications and injectable fillers that are approved for specific use by the FDA, but this 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. Examples of commonly accepted “Off-Label” use of drugs or devices include the use of aspirin for prevention of heart disease, retinoids for skin care, and injection of botulinum toxin for wrinkles around the eyes.

___ I acknowledge that I have been informed about the Off-Label FDA status of Restylane and I understand it is not experimental and accept its use.

ADDITIONAL TREATMENT NECESSARY

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of Restylane injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Restylane injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

FINANCIAL RESPONSIBILITIES

The cost of Restylane 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 material itself. 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.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed 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. Your physician may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the current state of medical knowledge. 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.

I have read the information regarding Restylane® injection in its entirety and have discussed the risks and benefits of dermal filler treatment with my physician and his/her representative at Dr. K’s Med Spa. **I understand the information provided and realize that results are not guaranteed and can vary.** I agree to my being treated with Restylane®. By also signing below gives your consent to this initial and all periodic treatments thereafter.

Patient’s Signature _____ Date: _____

I have discussed the risks and benefits of dermal filler treatment with this patient, have answered his/her questions, and find him/her an appropriate candidate for treatment with Restylane®.

Signature of Physician or Physician’s Representative: _____ Date: _____