

INFORMED CONSENT – RESTYLANE® INJECTION

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INFORMED CONSENT – RESTYLANE® INJECTION

INSTRUCTIONS

This is an informed-consent document which has been prepared to help your plastic surgeon inform you concerning Restylane® (Non-Animal Stabilized Hyaluronic Acid, *Medicis Aesthetics*) tissue filler injection therapy, its risks, and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for this procedure as proposed by your plastic surgeon and agreed upon by you.

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. 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, Medicis Aesthetics*). The hyaluronic acid in Restylane is biocompatible and is a totally non-animal product; there is little risk of animal-based disease transmission or allergic reaction.

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 treatments such as BOTOX®, or as an adjunct to a surgical procedure. 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 time.

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. Additional information concerning Restylane may be obtained from the package-insert sheets supplied by Medicis Aesthetics.

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, though unusual, 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. If you are considering laser treatment, chemical skin peeling or any other procedure based on a skin response after Restylane 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.

RISKS OF RESTYLANE 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: 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. Surgical procedures or other treatments may be recommended in addition to Restylane treatments.

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.

Combination of Procedures: In some situations, Botox® injections or other types of tissue filler materials may be used in addition to Restylane 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 Restylane is unknown.

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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.

ADDITIONAL ADVISORIES

Female Patient Information: It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Mental Health Disorders and Elective Surgery: 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, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

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. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. 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 the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with clotting and can cause more bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Alleve. It is very important not to stop drugs that interfere with platelets, such as Plavix, which is used after a stent. It is important if you have had a stent and are taking Plavix that you inform the plastic surgeon. Stopping Plavix may result in a heart attack, stroke and even death. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Travel Plans: Any surgery holds the risk of complications that may delay healing and delay your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

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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.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for Restylane injections used to treat medical conditions. Please carefully review your health insurance subscriber information pamphlet.

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. It is unlikely that Restylane injections to treat cosmetic problems would be 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.

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. Your plastic surgeon 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.

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

INFORMED CONSENT – RESTYLANE® INJECTION
CONSENT FOR SURGERY/ PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ and such assistants as may be selected to perform the following procedure or treatment: **RESTYLANE INJECTION** (list the anatomic areas where Restylane will be injected)

I have received the following information sheet:

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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 surgeon 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. All of my questions have been answered, and I understand the inherent (specific) risks of 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 medical-device registration, if applicable.
8. I understand that the surgeon's 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

<p>I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-10). I AM SATISFIED WITH THE EXPLANATION.</p> <p>_____</p> <p>Patient or Person Authorized to Sign for Patient</p> <p>Date _____ Witness _____</p>
