INFORMED CONSENT – RESTYLANE®, PERLANE® AND JUVEDERM® -- LILLIAN OVERMAN, MD

INSTRUCTIONS

This document will inform you about non-animal stabilized hyaluronic acids, such as Restylane® and Perlane® (by Medicis Aesthetics) and Juvederm® (by Allergan), their risks and alternative treatments. It is important that you read this information carefully and completely. Please sign each page, indicating that you have read that page.

GENERAL INFORMATION

Restylane®, Perlane® and Juvederm® are stabilized hyaluronic acids used to smooth moderate to severe facial wrinkles and folds or shape facial contours. Restylane®, Perlane® and Juvederm® have 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 in human soft tissues. Restylane®, Perlane® and Juvederm® are hyaluronic acids that have been synthetically produced by a process of bacterial fermentation, then chemically stabilized and purified. The hyaluronic acid found in Restylane®, Perlane® and Juvederm® is biocompatible and not an animal product so there is little risk of animal-based disease transmission or allergic reactions.

Restylane®, Perlane® and Juvederm® injections are customized for each patient, depending on his or her particular need and can be performed in multiple areas of the face. Restylane®, Perlane® and Juvederm® cannot stop the process of aging. They can, however, temporarily diminish the appearance of wrinkles and soft tissue depressions.

Restylane®, Perlane® and Juvederm® injections may be performed alone or in combination with other treatments such as Botox®. Restylane®, Perlane® and Juvederm® injections may require the use of regional nerve blocks or topical anesthetic application to diminish discomfort. Soft tissue fillers, including Restylane®, Perlane® and Juvederm®, 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®, Perlane® and Juvederm® over time. After Restylane®, Perlane® and Juvederm® are injected, they will be slowly absorbed by the body. The duration of the effect of Restylane®, Perlane® and Juvederm® injections is variable.

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ALTERNATIVE TREATMENTS

Alternatives to using hyaluronic acids, such as Restylane®, Perlane® and Juvederm®, include not treating skin wrinkles or soft tissue depressions by any means, treating them with lasers, chemical peels, dermabrasion, non-hyaluronic acid fillers or surgery. Risks and potential complications are also associated with these alternative forms of medical and surgical treatment.

THE IMPORTANCE OF YOUR UNDERSTANDING TREATMENT RISKS

It is important that you understand the risks and benefits of treatment with Restylane®, Perlane® and Juvederm® because your choice to undergo such treatment is based on the comparison of these risks to the potential benefits. Additional information may be obtained from the package-insert sheets supplied by Medicis Aesthetics and Allergan.

NORMAL OCCURRENCES DURING TISSUE FILLER INJECTIONS

- **Bleeding and Bruising** – It is possible, though unusual, to have a bleeding episode from an injection. Should you develop post-injection bleeding, emergency treatment or surgery may be necessary. Bruising in soft tissues may also occur. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginko biloba and other "herbs/homeopathic remedies" may increase the risk of bleeding and bruising. Do not take any of these products for seven days before or after Restylane®, Perlane® and Juvederm® injections unless you have been advised to do so by your cardiologist or primary care physician.
- **Swelling** – Swelling (edema) is a normal occurrence following the injection of Restylane®, Perlane® and Juvederm®. It usually decreases after a few days, but if it slow to resolve, medical treatment may be necessary.
- **Erythema (Skin Redness)** – Erythema occurs in the skin after injections. It can be present for a few days after the procedure.
- **Needle Marks** – Visible needle marks from injections occur normally and resolve in a few days.
- **Acneiform Skin Eruptions** – Acne-like skin eruptions can occur following the injection of Restylane®, Perlane® and Juvederm®. These generally resolve within a few days.

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NORMAL OCCURRENCES DURING TISSUE FILLER INJECTIONS continued

- **Skin Lumpiness** – Lumpiness can occur following the injection of Restylane®, Perlane® and Juvederm®. 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**– It may be possible to see Restylane®, Perlane® and Juvederm® through the skin if it is injected into areas where the skin is thin.
- **Asymmetry** – The human face is normally asymmetrical in its appearance and structure. 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 after Restylane®, Perlane® and Juvederm® injections. This may require additional injections.
- **Pain** – Discomfort associated with Restylane®, Perlane® and Juvederm® injections is normal and usually of short duration.
- **Skin Sensitivity** – Skin rash, itching, tenderness and swelling may occur following Restylane®, Perlane® and Juvederm® injections. After treatment, you should avoid exposing the treated area to excessive sun, UV lamps and extremely hot or cold temperatures until any initial swelling or redness has gone away. If you were to undergo laser treatment, chemical peels or any other procedure after Restylane®, Perlane® and Juvederm® treatment, there is a possible risk of an inflammatory reaction at the implant site.

RISKS OF RESTYLANE® AND PERLANE® INJECTIONS

- **Accidental Intra-Arterial Injection** –Restylane®, Perlane® and Juvederm® can accidentally be injected into arteries and block blood flow. This could cause necrosis in facial skin and other structures, loss of vision or other unknown consequences. This is a very serious, but rare occurrence.
- **Damage to Deeper Structures** – Deeper structures such as nerves and blood vessels may be damaged during the course of Restylane®, Perlane® and Juvederm® injections. Injury to deeper structures may be temporary or permanent.

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RISKS OF RESTYLANE® AND PERLANE® INJECTIONS contined

- **Infection** – Bacterial, fungal, and viral infections can occur following injection with Restylane®, Perlane® and Juvederm. One such infection is the reactivation of the herpes simplex virus commonly referred to as a cold sore. This can occur both in individuals who have had prior cold sores and those who have not. Please ask Dr. Overman for a Valtrex prescription if you plan to have an injection in an area where you have had a prior cold sore. Should any other type of skin infection occur, additional treatment including antibiotics may be necessary.
- **Allergic Reactions and Hypersensitivity** – As with all biologic products, allergic and anaphylactic reactions may occur. You should not have injections with Restylane®, Perlane® and Juvederm® if you have a history of multiple severe allergies, a history of anaphylaxis or allergies to gram-positive bacterial proteins. Allergic reactions may require additional treatment.
- **Scarring** – It is possible that injections with Restylane®, Perlane® and Juvederm could promote excessive scar formation so you should not receive these injections if you have a history of keloid formation or other forms of excessive healing at scars sites.
- **Granulomas** – Granulomas are masses that the body forms akin to scar tissue. Rarely, these may occur in the skin and deeper tissues after a Restylane®, Perlane® or Juvederm® injection. Should a granuloma develop, additional treatments including surgery may be necessary.
- **Skin Disorders** - In rare instances, granuloma, abscess, localized necrosis and urticaria have occurred after Restylane®, Perlane® and Juvederm® injections into areas with active inflammation or infection (e.g. cysts, pimples, rashes or hives).
- **Antibodies to Restylane®, Perlane® and Juvederm®** - If antibodies form to Restylane®, Perlane® or Juvederm, this could 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.
- **Anesthetic Reactions** – It is possible to have a reaction to the anesthetic applied before injection or from the lidocaine anesthetic mixed with Restylane®, Perlane® or Juvederm®. Such reactions include light-headedness, rapid heart rate (tachycardia) and fainting. Medical treatment of these conditions may be necessary.

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UNKNOWN CONSEQUENCES OF TREATMENT

- **Combination of Procedures** –The long term effect of combining injections of Restylane®, Perlane® and Juvederm® with other treatments (for example: non-hyaluronic acid fillers, Botox, laser, microdermabrasion, chemical peels or others) is unknown.
- **Unknown Risks** – The long term consequences of injecting Restylane®, Perlane® and Juvederm® are unknown. It is possible that complications may arise from the use of Restylane®, Perlane® and Juvederm® that are unknown and cannot be predicted.
- **Pregnancy and Nursing Mothers** – It is not known if Restylane®, Perlane® and Juvederm® are safe in pregnancy or if their breakdown products are excreted in human milk. Because the risk is unknown, pregnant women and nursing mothers should **not** receive Restylane®, Perlane® or Juvederm® injections.
- **Drug Interactions** – It is not known if Restylane®, Perlane® and Juvederm® react with other drugs within the body.

DISAPPOINTING RESULTS

- **Under/Over Correction** – Injection of Restylane®, Perlane® and Juvederm® may not achieve your desired outcome. The amount of correction may be inadequate or excessive. If under correction occurs, you may be advised to consider additional injections of filler.
- **Migration of Restylane®, Perlane® and Juvederm®** - Restylane®, Perlane® and Juvederm® may migrate from their original injection site and produce visible fullness in adjacent tissue or other unintended effects.
- **Unsatisfactory Result** - Restylane®, Perlane® and Juvederm® injections may not result in the outcome you expect. It is possible that your tissue's response may be poor or inadequate. Additional Restylane®, Perlane® or Juvederm® injections or surgery may be necessary to achieve your desired result.

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TREATMENT IS NOT PERMANENT - Restylane®, Perlane® and Juvederm® injections should not be considered permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the Restylane®, Perlane® and Juvederm® are slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. It is necessary to continue to receive injections of filler to maintain the effect. Despite such injections, alterations in the face may still occur as the result of aging, weight loss or gain, sun exposure, or other circumstances and may necessitate future surgery or other treatments. Restylane®, Perlane® and Juvederm® injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

DISCLAIMER – This document is designed to inform you about Restylane®, Perlane® and Juvederm® injections and disclose the associated risks and alternative forms of treatment. It should not be regarded as all-inclusive because it is not anticipate all possible risks and alternative forms of treatment. This document is 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 have read all of the above information carefully and have all of your questions answered before signing this consent form.

1) **I HEREBY AUTHORIZE Dr. Overman to inject Restylane®, Perlane® or Juvederm®.**
2) **I consent to the administration of anesthetics and understand that all forms of anesthesia involve risk and possible complications include injury and rarely death.**
3) **I am aware that Restylane®, Perlane® and Juvederm® contain Lidocaine.**
4) **I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.**
5) **I understand that there are alternative methods of treatment.**
6) **I understand that there are risks to the proposed treatment**

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