POLO
HEALTH + LONGEVITY CENTRE

# MEDI-SPA INFORMED CONSENT – RESTYLANE®, RESTYLANE-L®, PERLANE®, OR PERLANE-L® INJECTIONS

**INSTRUCTIONS**
This is an informed-consent document which has been prepared to help your doctor inform you concerning Restylane® and Perlane® (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 doctor and agreed upon by you.

**GENERAL INFORMATION**
Restylane and Perlane are stabilized hyaluronic acids used to smooth moderate to severe facial wrinkles and folds around the nose and mouth or shape facial contours. Restylane and Perlane 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 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 and Perlane is biocompatible and is a totally non-animal product; there is little risk of animal-based disease transmission or allergic reaction.

Restylane and Perlane injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the lower face. Restylane and Perlane cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles and soft tissue depressions.
Restylane and Perlane 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 and Perlane injections may require topical anesthetic to diminish discomfort. Soft tissue fillers, including Restylane and Perlane, 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 or Perlane over time. Restylane or Perlane once injected will be slowly absorbed by the body. The length of effect for Restylane or Perlane injections is variable.

**RISKS OF RESTYLANE® OR PERLANE® 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 or Perlane injections. Additional information concerning Restylane or Perlane 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 or Perlane. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve Restylane or Perlane.

**NORMAL OCCURRENCES DURING TISSUE FILLER INJECTIONS, INCLUDING RESTYLANE AND PERLANE**
**Bleeding and Bruising-** It is possible, though unusual, to have a bleeding episode from a Restylane or Perlane 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 or Perlane 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 or Perlane. 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 filer injections. There can be a variation from one side to the other in terms of the response to Restylane or Perlane injection. This may require additional injections.

**Pain-** Discomfort associated with Restylane or Perlane injections is normal and usually of short duration.

**Skin Sensitivity-** Skin rash, itching, tenderness and swelling may occur following Restylane/Restylane-L or Perlane 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 or Perlane 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® OR PERLANE® 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 or Perlane 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. Restylane and Perlane 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. Restylane-L and Perlane-L should not be used in patients with known allergy to lidocaine.

**Scarring-** Restylane and Perlane 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 or Perlane injection are extremely rare. Should these occur, additional treatments including surgery may be necessary.

**Skin Disorders-** Restylane and Perlane 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.

How would you like to pay? Cash____| Credit Card:_____| Name on the Credit Card:_____Expiry date:_____

_____
Patient Initials

Credit Card #:_____security code on the back_____

**Accidental Intra-Arterial Injection-** It is extremely rare that during the course of injection, Restylane or Perlane 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 or Perlane is unknown and not predictable.

**Under / Over Correction-** The injection of soft tissue fillers including Restylane or Perlane 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/Perlane-** Restylane and Perlane 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.

**ADDITIONAL ADVISORIES**

**Unsatisfactory Result-** Restylane and Perlane 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/Perlane injection(s). Additional Restylane/Perlane injections may be necessary. Other treatments may be recommended in additional to Restylane/Perlane treatments.

**Unknown Risks-** The long term effect of Restylane/Perlane beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of Restylane/Perlane 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 or Perlane 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 or Perlane is unknown.

**Pregnancy and Nursing Mothers-** Animal reproduction studies have not been performed to determine if Restylane or Perlane could produce fetal harm. It is not known if Restylane/Perlane or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive Restylane or Perlane treatments.

**Drug Interactions-** It is not known if Restylane or Perlane reacts with other drugs within the body.

**Long-Term Effects-** Restylane and Perlane injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the Restylane and Perlane material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing Restylane or Perlane treatment (injections) is necessary in order to maintain the effect of Restylane/Perlane. 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 and Perlane injections. Other treatments may be necessary. Restylane and Perlane injection does not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

**AFTERCARE**

Specific aftercare instructions will be provided for you. It is important that these instructions are followed to avoid possible complications.

**HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for Restylane or Perlane 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 or Perlane injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Restylane and Perlane injections. Other complications and risks can occur but are even more uncommon. Should complications occur, other treatments may be necessary. The practice of medicine 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 or Perlane 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 Restylane or Perlane material itself. It is unlikely that Restylane or Perlane injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from Restylane or Perlane injections.

**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 doctor 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 below.**

## CONSENT FOR PROCEDURE OR TREATMENT

1. I hereby authorize Dr._____and such assistants as may be selected to perform the following procedure or treatment:
   RESTYLANE or PERLANE INJECTION (list the anatomic areas where Restylane or Perlane will be injected i.e. nasolabial folds)

2. I have received the following information sheet: INFORMED CONSENT - RESTYLANE/PERLANE INJECTION

3. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.

4. I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. If a secondary procedure is necessary, further expenditure will be required.

5. 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

**I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-5). I AM SATISFIED WITH THE EXPLANATION.**

Patient or Person Authorized to Sign for Patient _____

Date_____Witness _____