

## **CONSENT TO RECEIVE RESTYLANE® INJECTION**

### **A. PURPOSE AND BACKGROUND**

As my patient, you have requested my administration of Restylane®; a stabilized hyaluronic acid used in the correction of moderate to severe facial wrinkles and folds. All medical and cosmetic procedures carry risks and may cause complications. The purpose of this document is to make you aware of the nature of the procedure and its risks in advance, so that you can decide whether or not to go forward with the procedure.

### **B. PROCEDURE**

1. This product is administered via a syringe, or injection, into the areas of the face sought to be filled with the hyaluronic acid to eliminate or reduce the wrinkles and folds.
2. An anesthetic, numbing medicine used to reduce the discomfort of the injection may or may not be used.
3. The treatment site(s) is washed first with an antiseptic (cleansing) solution.
4. Restylane is a clear transparent gel that is injected under your skin into the tissue of your face using a thin gauge (30 G) needle.
5. The depth of the injection(s) will depend on the depth of the wrinkle(s) and its location(s).
6. Multiple injections might be made depending on the site, depth of the wrinkle, and technique used.
7. Following each injection, the injector should gently massage the correction site to conform to the contour of the surrounding tissues.
8. If the treated area is swollen directly after the injection, ice may be applied on the site for a short period.
9. After the first treatment, additional treatments of Restylane may be necessary to achieve the desired level of correction.
10. Periodic touch-up injections help sustain the desired level of correction.

### **C. RISKS/DISCOMFORT**

1. Although a very thin needle is used, common injection-related reactions could occur. These could include: some initial swelling, pain, itching, discoloration, bruising or tenderness at the injection site. You could experience increased bruising or bleeding at the injection site if you are using substances that reduce blood clotting such as aspirin or other non-steroidal anti-inflammatory drugs such as Advil®.
2. These reactions generally lessen or disappear within a few days but may last for a week or longer.
3. As with all injections, this procedure carries the risk of infection. The syringe is sterile and standard precautions associated with injectable materials have been taken.
4. Some visible lumps may occur temporarily following the injection.
5. Some patients may experience additional swelling or tenderness at the injection site and in rare occasions, pustules might form. These reactions might last for as long as approximately 2 weeks, and in appropriate cases may need to be treated with oral corticosteroids or other therapy.
6. Restylane should not be used in patients who have experienced this hypersensitivity, those with severe allergies, and should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives).

7. Restylane should not be used in areas other than the tissues of the face.
8. 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.
9. Most patients are pleased with the results of Restylane use. However, like any cosmetic procedure, there is no guarantee that you will be completely satisfied. There is no guarantee that wrinkles and folds will disappear completely, or that you will not require additional treatments to achieve the results you seek. While the effects of Restylane use can last longer than other comparable treatments, the procedure is still temporary. Additional treatments will be required periodically, generally within 6 months to one year, involving additional injections for the effect to continue.
10. 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.

#### **D. BENEFITS**

Restylane has been shown to be safe and effective when compared to collagen skin implants and related products to fill in wrinkles, lines and folds in the skin on the face. Its effect, once the optimal location and pattern of cosmetic use is established, can last 6 months or longer without the need for re-administration.

#### **E. ALTERNATIVES**

This is strictly a voluntary cosmetic procedure. No treatment is necessary or required. Other alternative treatments which vary in sensitivity, effect and duration include: animal-derived collagen filler products, dermal fillers derived from the patient's own fat tissues, synthetic plastic permanent implants, or bacterial toxins.

#### **F. COST/PAYMENT**

The cost of treatment will be billed to you individually. Since most uses of Restylane are considered cosmetic, they are generally not reimbursable by government or private health care insurers.

#### **G. QUESTIONS**

This procedure has been explained to you by your physician, or the person who signed below and your questions were answered. If you have any other questions about this product or procedure, you may call Dr. \_\_\_\_\_ at ( ) \_\_\_\_-\_\_\_\_, or his/her associate at ( ) \_\_\_\_-\_\_\_\_.

#### **H. CONSENT**

You have been given a copy of this consent form. Your consent and authorization for this procedure is strictly voluntary. By signing this informed consent form, you hereby grant authority to your physician to perform Facial Augmentation and Filler Therapy/Injections using Restylane and/or to administer any related treatment as may be deemed necessary or advisable in the diagnosis and treatment of your condition.

The nature and purpose of this procedure, with possible alternative methods of treatment as well as complications, have been fully explained to your satisfaction. No guarantee has been given by anyone as to the results that may be obtained by this treatment.

I have read this informed consent and certify that I understand its contents in full. I have had enough time to consider the information from my physician and feel that I am sufficiently advised to consent to this procedure. I hereby give my consent to this procedure and have been asked to sign this form after my discussion with the physician.

PATIENT SIGNATURE: \_\_\_\_\_

PHYSICIAN SIGNATURE: \_\_\_\_\_

DATE: \_\_\_\_\_