GULF COAST PLASTIC SURGERY *Gregory P. Pisarski, MD*

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Injectable Dermal Fillers

(Restylane Line - Lyft®,Defyne®,Kysse®,Contour®)
(RHA Collection – RHA Density™, RHA®2, RHA®3, RHA®4)

Consent form

Name:_____ Date: _____

INTRODUCTION

This is an informed consent document, which has been prepared to help inform you about the Restylane family of products; 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. The Restylane products have 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.

INDICATIONS AND PROCEDURE

Restylane products are indicated for the correction of contour deficiencies of soft tissue in patients 21 years or older. It is considered off label use for patients under 21 years of age. Two or more implant sessions may be required to achieve the desired effect. Restylane products has been employed successfully in many areas of the body to correct distensible acne scars, atrophy from disease or trauma, glabellar frown lines, nasolabial folds, or defects secondary to rhinoplasty, skin graft or other surgery, and other soft tissue defects. Touch-up injections at approximately 6 to 9 month (intervals will be required to maintain maximum correction. The interval at which touch-up injections are needed depends on the nature of the defect, amount of filler introduced, the plane of placement and the stresses that may exist at corrected sites.

- Restylane products are a clear transparent gel that is injected under your skin into the tissue of your face with a very fine needle and/or microcannula into the areas of the face sought to be filled with the hyaluronic acid to eliminate or reduce the wrinkles and folds.
- An anesthesia, numbing medicine used to reduce the discomfort of the injection, may or may not be used.
- The treatment site(s) is washed first with an antiseptic (cleansing) solution.
- The depth of the injection(s) will depend on the depth of the wrinkle(s) and its location(s). Multiple injections might be made depending on the site, depth of the wrinkle, and technique used.
- Following each injection, the injector may massage the correction site to conform to the contour of the tissues.
- If the treated area is swollen directly after the injection, ice may be applied on the site for a short period.
- After the first treatment, additional treatments of filler may be necessary to achieve the desired level of correction.
- Periodic touch-up injections help sustain the desired level of correction

POTENTIAL RISKS

- Although a very thin needle is used, common injection-related reactions could occur. These 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, as well as vitamins and herbal products. These reactions generally lessen or disappear within a few days but may last for a week or longer.
- Another risk associated with these products is unintentional injection into a blood vessel, which is rare but can occur. The complications can be serious and may be permanent. These complications can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin.
- 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.
- Some may experience additional swelling or tenderness at the injection site and in rare occasions, pustules (blister) might form. These reactions might last for as long as approximately 2 weeks, and in appropriate cases

may need to be treated with oral corticosteriods or other therapy. In rare cases (fewer than 1 in 15000) granuloma formation, superficial necrosis, and urticaria (hives) have been reported.

- Some visible lumps may occur temporarily following the injection.
- Restylane products should not be used in patients who have experienced this hypersensitivity, those with severe allergies, or in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives).
- If you are considering laser treatment, chemical skin peeling or any other procedure based on a skin response after Restylane products, 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.
- Most patients are pleased with the results of Restylane products. 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 products can last longer than other comparable treatments, the procedure is temporary.
- 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 prone to cold sores/fever blisters, additional measures may be necessary to prevent a break out - please notify Dr. Pisarski and staff if you have a history of cold sores/fever blisters.
- The major contraindications to the use of a filler include active infection near the site of injection and a known allergy/hypersensitivity to the material or to the lidocaine mixed in the syringe of the filler. Little research has been conducted on the effects and safety of injectables and fillers for pregnant or breastfeeding women. Because of this lack of information, the FDA and many doctors advise pregnant women to wait until they've finished breastfeeding (if they plan to) before getting injectables or fillers.

ALTERNATIVES

This is strictly a voluntary cosmetic procedure. 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 that can paralyze muscles that cause some wrinkles.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed treatment along with disclosure of risk and alternative forms of treatment. 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 risk encountered. Your physician may provide you with additional or different information that is based on all the facts in your particular case and the state of medical knowledge at the time.

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 changes 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 statement.

CONSENT

I understand that my consent and authorization for this procedure is strictly voluntary. By signing this informed consent form, I hereby grant authority to Dr. Pisarski to perform Facial Augmentation and Filler Therapy/Injections using / Restylane products and/or to administer any related treatment as deemed necessary or advisable. The nature and purpose of this procedure, with possible alternative methods of treatment as well as complications, have been fully explained to my satisfaction. No guarantee has been given 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.

If pre/post-operative photos are taken of the treatment for record purposes, I understand that these photos will be the property of the attending physician. I consent to the photographing of the procedure for medical, scientific or educational purposes provided the pictures do not reveal my identity. For purposes of education, I consent to the admittance of observers during the procedure. I understand: the treatment that will be provided to me and the alternative procedures or methods of treatment. I have also been given specific follow-up instructions and will comply with these.

I certify that I have read and understand this consent and that all blanks were filled in prior to my signature.

_____	_____	_____
Signature - Patient	Print Name	Date
_____	_____	_____
Signature – Physician	Print Name/Title	Date