**DERMAL FILLER CONSENT**

Dermal Fillers (Belotero, Juvederm, Revanesse, Radiesse, Restylane)

**PURPOSE AND BACKGROUND**

Dermal Fillers are a stabilized hyaluronic acid gel, or a Calcium hydroxylapatite gel used for the correction of moderate to severe facial wrinkles and folds, to add volume to the lips, improve the appearance of recessed scars, and contour facial features that have lost their fullness due to aging, sun exposure, illness, etc. These dermal fillers are injected into the skin with a very fine needle or a cannula. The products produce a natural volume under the wrinkle, which is lifted up and smoothed out. The results can often be seen immediately. 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 so that you can decide whether or not to go forward with the procedure. (Note: “Dermal Filler” in this form refers to Juvederm, Radiesse, Restylane, Belotero, Perlane, and other similar products.)

**PREGNANCY, ALLERGIES AND DISEASE**

You should not get fillers if you are pregnant or trying to get pregnant or nursing, as the effects of the fillers on developing fetus/baby has not been determined. You should not be taking blood thinners. You should not have any major illnesses which would prohibit you from receiving any dermal fillers. You should not have multiple allergies or high sensitivity to medications, including but not limited to Lidocaine. You should not have had cosmetic surgery on the area that you want to have fillers in, as prior surgeries lead to change in blood supply of the region and make you more prone to getting clogged blood vessels and necrosis of skin or blindness. You should not have active infection or inflammation in the area you want treated. You should not have any permanent filler such as Artefill, Belafill or Silicone, as injection of another filler can trigger inflammation or infection of the old implant.

**PROCEDURE**

* This product is administered via a syringe, or cannula, into the areas of the face sought to be filled with the hyaluronic acid to eliminate or reduce the wrinkles and folds.
* A topical anesthetic, numbing medicine is used to reduce the discomfort of the injection and the filler also has an anesthetic medication in it.
* The treatment site(s) is washed first with an antiseptic (cleansing) solution.
* Dermal fillers are clear transparent gels that are injected under your skin into the tissue of your face using a thin gauge needle or cannula.
* 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 would gently massage the correction site to conform the filler to the contour of the surrounding tissues.
* If the treated area is swollen directly after the injection, ice may be applied on the site for a short period of time.
* After the first treatment, additional treatments of dermal fillers may be necessary to achieve the desired level of correction.
* Periodic enhancement injections help sustain the desired level of correction.

**RISKS/COMPLICATIONS**

* 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®, Aleve or supplements like Vit E, flaxseed, omega 3 supplements, gingko, and ginseng. These reactions generally lessen or disappear within a few days but may last for two weeks or longer.
* As with all injections, this procedure carries the risk of infection. The syringe is sterile and standard precautions associated with injectable materials will be taken. If infection happens you will need oral antibiotics for treatment.
* Reactivation of Herpes (cold sores) especially if injections are done in and around the lips. To prevent this, it is recommended that you take medications starting 2 days prior to treatment and for one week after.
* Some visible lumps may occur temporarily following the injection and they usually resolve after a few weeks. But sometimes bigger lumps may last for a very long time (granuloma formation) and this may be related to chronic infections or inflammatory response of the body to the filler. The granulomas can be dissolved with an enzyme if needed or may need to be extracted surgically. If the filler is applied too superficially or the skin is too thin it would look blue/purple (Tyndall effect).
* Migration: filler may move from the place where it is injected due to gravity, rubbing or other reasons.
* Allergic Reactions and Hypersensitivity: As with all biologic products, allergic and systemic anaphylactic reactions may occur. Fillers 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. Some patients may experience allergic reactions and additional swelling or tenderness at the injection site and in rare occasions, pustules might form. These reactions might last for 2 weeks or longer, and in severe cases may need to be treated with oral corticosteroids or other medications.
* Under / Over Correction: The injection of soft tissue fillers 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.
* 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 injection. Addressing this may require additional injections.
* On very rare occasions the dermal filler may be accidentally injected into a blood vessel and if this happens, occlusion of the blood vessel and necrosis of the skin supplied by the vessel can happen. Also, if the dermal filler finds its way into the arteries of the eye it can cause blindness. These are very rare occasions and risk of them is estimated to be 0.1-1 per 1000, 000 injections. If this happens an enzyme will be injected in the area to dissolve the filler, warm compress and vigorous massaging will be applied to the area to help reverse the problem, but it is not always successful.
* Dermal fillers should not be used in patients who have experienced hypersensitivity, those with severe allergies, and should not be used 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 dermal filler 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. These treatments should be at least two weeks apart.
* Most patients are pleased with the results of dermal fillers 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 treatment to achieve the results you seek. While the effects of Dermal fillers use can last longer than other comparable treatments, the procedure is still temporary. Additional treatments will be required periodically, generally within 4-6 months to one year, involving additional injections for the effect to continue.
* 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.

**TEMPORARY NATURE OF RESULTS**

Dermal fillers 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. Their effect, once the optimal location and pattern of cosmetic use is established, can last 4- 6 months or longer without the need for re-administration. The duration of effects is dependent on many factors including but not limited to: age, sex, tissue conditions, site of administration and movements in the area, general health, life style such as smoking, and sun exposure. The correction, depending on these factors many last 4-6 months and in some cases shorter and some cases longer.

**ALTERNATIVES**

This is strictly a voluntary cosmetic procedure. No treatment is necessary or required. 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 also associated with alternative forms of medical or surgical treatment.

**COST/PAYMENT**

The cost of treatment will be billed to you individually. Once you agree to treatment you agree to pay the amount specified for that treatment. There will be no refunds provided even if you are not satisfied with the results. Since use of dermal fillers are considered cosmetic, they are not reimbursable by government or private health care insurers. I understand that this procedure is an “elective” cosmetic procedure and that payment is my responsibility. Any expenses which may be incurred by medical care I elect to receive outside of this office, such as, but not limited to dissatisfaction of my treatment outcome will be my sole financial responsibility. If a touch-up treatment is requested/required, patient is responsible for the cost of that additional treatment. Payment in full for all treatments is required at the time of service and is non-refundable. You may request a price quote before your treatment

**PHOTOGRAPHS**

I consent to the taking of clinical photographs and/or videos and their use for scientific purposes both in publications and presentations. I understand my identity will be protected, and the pictures are the property of the physician.

**RESULTS**

I am aware that full correction is usually not possible and that follow-up enhancement treatments will be needed to maintain the full effects. I have been instructed in and understand post-treatment instructions and have been given a copy of them.

I hereby voluntarily consent to treatment. I have read the above and understand it. My questions have been answered satisfactorily. I accept the risks and complication of the procedure.

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 healthcare practitioner 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 healthcare practitioner.

PATIENT NAME (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

HEALTHCARE/PRACTITIONER SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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