KORIN KORMAN | Body+Beauty Lab

SCULPTRA® INFORMED CONSENT

This is an informed-consent document which has been prepared to help your Medical Injector inform you concerning Sculptra® Dermal Filler injection, its risks, likely effects and alternative treatments.

It is important that you read this information carefully and completely. Please sign the consent for this procedure as proposed by your Medical Injector and agreed upon by you, indicating that you have read the informed consent.

I, _____ authorize Medical Injector _____ to perform the following procedure: **Sculptra® Dermal Filler Injection**.

To correct or enhance the following areas:

Anterior Cheek		Marionette Lines		Hands	
Lateral Cheek		Oral Commissures		Earlobes	
Nasal Jugal Grooves		Chin/Mental Crease		Jawline	
Corrugators		Submalars		Crow's Feet	
Temples		Lips		Brow Lines	
Nasal Labial Fold		Nose		Preauricular	
Other		Other		Other	

INDICATIONS AND PURPOSE OF THE PROCEDURE

Sculptra® injectable gel (Poly-L-Lactic Acid PLLA) is in the category of "bio-stimulators" and has been safely used in orthopedics since the mid-nineties and has been used in Europe since 1999 for cosmetic correction of scars and wrinkles. Sculptra® is approved by the United States Food and Drug Administration, and is biocompatible, biodegradeable, synthetic polymer from the alpha-hydroxy-acid family. Sculptra® is used for the temporary cosmetic treatment and correction of moderate to severe facial wrinkles, folds (such as the nasolabial folds around the nose and mouth), soft tissue depressions, for restoring volume and to shape facial contours. It works differently from other injectable products as tiny particles of PLLA are diluted in a suspension of sterile water, carefully implanted in the skin, and then molded for optimal results. The particles of PLLA stimulate the formation of new collagen in the skin adding volume over time. Sculptra® should not be injected into the red area of the eyes or of the lips. Sculptra® may require a series of 3-6 treatments every 6-8 weeks. Typically, improvement in contours occurs gradually over 2-6 months. Treatment result last up to 2 years. Sculptra® filler cannot stop the process of aging, however they can temporarily diminish the look of wrinkles and soft tissue depressions. Without periodic touchup injections, the correction will subside gradually, and the skin will look as it did before the treatment. Subsequent alterations in face and eyelid appearance may occur as a result of aging, weight loss or weight gain, sun exposure, pregnancy, menopause or other circumstances not related to dermal filler injections.

Filler injections may be performed as a singular procedure, in combination with other injectable treatments, or as an adjunct to a surgical procedure. Filler injections require regional nerve blocks or

local anesthetic injections to diminish discomfort. Any history of an allergy to local anesthetic must be conveyed to the Medical Injector, as the possibility of light-headedness, rapid heartbeat and fainting may occur.

SIDE EFFECTS AND COMPLICATIONS

Every procedure involves a certain amount of risk and possible complications associated with them. Although the majority of clients do not experience these complications you should discuss each of them with your Medical Injector to understand risks, potential complications, limitations and consequences.

Side effects, risks and complications associated with dermal filler injections include but are not limited to:

1. **Bruising, Redness, Swelling, Itching, Tenderness and Pain:** I understand that there is a risk of bruising, redness, swelling, itching and pain associated with the procedure, as well as temporary skin discoloration and needle marks. These symptoms are usually mild and last less than a week but can last longer. Clients who are using medications that can prolong bleeding, such as aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, or certain vitamins and herbal supplements, may experience increased bruising or bleeding at the injection site. Seek emergency medical treatment for post injection bleeding.

2. **Nodules and Palpable Material:** I understand that there is a risk that small lumps may form under my skin due to the Sculptra® Dermal Filler material collecting in one area, which may or may not be visible, and may occur within the first 6 to 12 months after treatment. Visible bumps may be red in the treated area. Some lumps have had to be treated with corticosteroid injections or surgery (rare). I also understand that I may be able to feel Sculptra® filler material in the area where the material has been injected. Any foreign material injected into the body may create the possibility of swelling or other local reactions to a filler material.

3. **Accidental Injection into a Blood Vessel:** Although very rare due to the thin and watery suspension, I understand that Sculptra® Dermal Filler can be accidentally injected into a blood vessel (arterial structures) which may block the blood vessel (flow of blood) and cause damage of potentially large areas of distant tissue, or potentially even a heart attack, stroke or blindness.

4. **Infection:** As with all transcutaneous procedures, I understand that injection of any filler material carries the risk of infection.

5. **History of Herpes Infection**: I understand that there is a risk that injection of any filler material carries the risk of a recurrence of an outbreak of herpes simplex virus (fever blisters/cold sores/ shingles) and that the outbreak may be severe in nature. I have disclosed to the health care provider my medical history and in particular, disclosed prior herpes outbreaks. Medications must be taken prior to and following the treatment in order to suppress an infection from the herpes virus. Should an infection occur, antibiotics may be necessary.

6. **Skin Infection:** I understand that Restylane® and/or Sculptra® Dermal Filler should not be used in areas of active infection (cysts, pimples, rashes or hives) or on those who are on immunosuppressive therapy.

7. **Allergic Reactions:** I understand that Sculptra® Dermal Filler should not be used in clients with severe allergies, a history of anaphylaxis, history or presence of multiple severe

allergies, hypersensitivity to any of the ingredients in Sculptra® Dermal Filler, especially carboxymethylcellulose and nonpyrogenic mannitol.

8. **Skin Necrosis:** It is very unusual to experience death of skin and deeper soft tissues after injections. Skin necrosis can produce unacceptable scarring. Should this complication occur, additional treatments or surgery may be necessary.

9. **Migration and Asymmetry:** Although very rare, I understand that Sculptra® Dermal Filler, as with any filler material, may move from the place where it was injected, resulting in unintended effects. The human face is normally asymmetrical in appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filler injections, there can be variations from one side to the other in terms of the response to injection.

10. **Duration of Effect:** I understand that the outcome of treatment with Sculptra® Dermal Filler will vary among clients. In some instances, additional treatments may be necessary to achieve the desired outcome.

11. **Concomitant Dermal Therapies:** I understand that the safety of Sculptra® Dermal Filler with concomitant Dermal Therapies such as epilation, UV radiation, laser, mechanical or chemical peeling procedures has not been evaluated in controlled clinical trials. If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with Sculptra® Dermal Filler, before the skin has healed completely, there is an increased risk of inflammatory reaction at the injection site.

12. **Keloids/Scarring:** I understand that the safety of Sculptra® Dermal Filler in clients with known susceptibility to keloid formation or hypertrophic scarring has not been studied.

13. **Pregnancy/Age:** I understand that the safety of Sculptra® Dermal Filler for use during pregnancy and in breastfeeding females, or in clients 21 years of age has not been studied, and therefore should not be used while pregnant, nursing or under the age of 21.

14. **Interactions:** I understand that the interaction of Sculptra® Dermal Filler with drugs or other substances or implants has not been studied.

15. **Unsatisfactory Results:** Not all wrinkles can be adequately treated with dermal fillers alone. There is the possibility of poor or inadequate response from filler injections. Other surgical procedures or treatments may be needed to improve wrinkles and folds, including wrinkle creams, laser skin resurfacing, other types of dermal fillers or bacterial toxins. Although good results are expected, there is no guarantee or warranty expressed or implied.

CONTRAINDICATIONS

Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba and other herbs/homeopathic remedies may contribute to a greater risk of bleeding and bruising problem. Do not take these for ten days before or after Sculptra® Dermal Filler injections.

As with any injection into the head or neck, the injected material may be inadvertently implanted in a blood vessel, which could cause occlusion, infarction, or embolic phenomena.

I understand that I should minimize exposure of the treated area to the sun, heat and extreme cold weather for approximately 24 hours after treatment or until any initial swelling or redness goes away and puncture sites have healed. Within the first 24 hours, you should avoid strenuous exercise. You should ask your healthcare provider when make-up may be applied after treatment.

I understand the above, and have had the risks, complications, benefits, and alternatives explained to me by the Medical Injector. No guarantees about results have been made.

CONSENT

I understand and agree that all services rendered will be charged directly to me, and I am personally responsible for payment. I further agree, in the event of non-payment, to bear the cost of collection, and/or court costs and reasonable legal fees should they be required. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the injections and will also be your responsibility.

I agree to follow up with Body+Beauty Lab at the recommended intervals to monitor the effectiveness of the treatment, and to contact Body+Beauty Lab to advise of any change in my condition or any problem I may experience.

In signing this consent for this procedure, you acknowledge that you have read the informed consent and have been informed about its risks and consequences and accept responsibility for the clinical decisions that have been made, along with the financial costs of all treatments and future treatments. I understand that I have the right not to consent to this treatment and that my consent is voluntary. I hereby release the Medical Director, Medical Injector and Body+Beauty Lab from liability associated with this procedure. I give my informed consent for Sculptra® Dermal Filler injection today as well as future treatments as needed.

Client Signature _____ **Date** _____

Medical Injector Signature_____ **Date** _____