



# SCULPTRA®

## AFTERCARE AND CONSENT FORM

### Procedural Description

Sculptra® Aesthetic is an FDA-approved injectable poly-L-lactic acid (PLLA) implant in the form of a sterile apyrogenic suspension. Poly-L-lactic acid is a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy acid family. Poly-L-lactic acid has been used medically for many years in dissolvable sutures. As a poly-L-lactic acid (PLLA) collagen stimulator, Sculptra helps restore the deep, underlying structure of the skin to diminish facial wrinkles. Sculptra works with your body within the deep dermis to help revitalize collagen production and help restore your skin's inner structure and volume. Correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern injection technique is appropriate. As the Sculptra PLLA microparticles are absorbed, they help stimulate collagen production. Rebuilt collagen strands begin gradually helping to restore facial volume and the look of fullness to wrinkles and folds. It is commonly used along the perimeters of the face to volumize and lift.

The results of Sculptra® are not immediate. Your aesthetic provider will decide the appropriate number of treatment sessions and the amount of Sculptra® needed at each session. Once injected, Sculptra® will be slowly absorbed by the body. The length of effect for Sculptra® is variable. Aging comes with diminished collagen production, which is why it becomes harder and harder to maintain good skin as you age as the skin doesn't have the same resilience and fullness it did during your younger years.

Sculptra® is famous for its ability to stimulate collagen. It works as a biostimulator for collagen production thereby restoring what was lost during aging and rebuilds and reinforces the structural foundation of your skin.

### What's the Difference Between Dermal Fillers and Sculptra?

Sculptra has a liquid consistency and is injected underneath the skin. Once injected, Sculptra incorporates into the tissues and stimulates your body's natural production of collagen. On the other hand, dermal fillers are made of Hyaluronic acid designed to hold its shape in the form of a gel-like substance. Dermal fillers do not stimulate collagen production but rather are meant to temporarily replace missing volume. The effects of dermal filler are apparent immediately. Whereas the effects of Sculptra happen gradually since it takes time for the body to build collagen.

Both Dermal filler and Sculptra are designed to address lost volume, fine lines, folds, and wrinkles. Due to the aging process, environmental stressors, and our genetic predisposition, we suffer from loss of collagen at a rate of about 1% annually after the age of 20. Loss of collagen leads to thinning of skin which results in the formation of wrinkles and folds. Collagen is a fibrous protein in the deep dermal layer that gives our skin structural support and helps to maintain the shape, moisture, and elasticity of the skin. A healthy supply of collagen is the source of smooth skin and a youthful appearance.

### Before Your Treatment

- Avoid the use of Aspirin, NSAIDS, Ginko Biloba, Garlic Supplements, Green Tea, Flax Oil, Cod Liver Oil, Vitamins A and E, and essential fatty acids for up to 1 week pre- and post-injection as they will increase your risk of bruising.
- Do not drink alcoholic beverages 24 hours before (or after) your treatment to avoid extra bruising.
- You may take Arnica tablets 2-3 days prior to your injection to reduce the risk of bruising.

- Do not apply products that are potentially irritating for 2 -3 days before and after treatment (examples- tretinoin/retin-a, glycolic acid, benzoyl peroxide, hydroquinone).
- Do not use the above-stated if you are pregnant or breastfeeding or are allergic to any of its ingredients. Please inform your provider if you have any questions about this prior to the treatment.
- If you have a history of Herpes or cold sores, a course of antiviral medication before and after treatment is required. Please call our office for a prescription.

## What to Expect During Treatment

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- Arrive with a clean face. Please do not wear makeup.
- You may experience a mild amount of tenderness or stinging during and following injections.
- Redness and swelling are normal. Some bruising may also be visible.
- Depending upon the area(s) treated and product(s) used, you may feel “firmness” in the treated area(s) for 1 to 2 weeks after treatment. Over time, the area(s) will soften and “settle.”

## Post-Treatment Instructions

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- Ice (but avoid firm pressure) for 15 minutes 3 times the day of treatment.
- You may take Acetaminophen/Tylenol if you experience any mild tenderness/discomfort.
- Massage the areas 5 times a day, for 5 minutes each time, for 5 days after treatment.
- After treatment, there will be moderate swelling and redness with the possibility of bruising. These symptoms will resolve in about 7 days.
- You may apply or take Arnica tablets to help decrease the amount of bruising.
- Avoid extended UV exposure until any redness/swelling has subsided. Apply SPF 40+.
- Avoid strenuous exercise for 24 hours to reduce bruising. You may resume other normal activities/routines immediately.
- Avoid laser, IPL/BBL, or skin tightening treatments of the area for at least 2-3 weeks.
- You may continue your topical products as mentioned above 1 week after injection.

## Sculptra® Consent Form

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The nature of the Sculptra procedure has been explained to me. I understand that just as there may be benefits from the procedure, all procedures involve risk to some degree. 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 the potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your provider to make sure you understand the risks, potential complications, limitations, and consequences of treatment. Additional information concerning Sculptra® may be obtained from the package insert supplied by Galderma that your provider can share with you. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with facial filler. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The possibility of additional risk factors or complications attributable to the use of biostimulators may be discovered. 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. There is the possibility of a poor or inadequate response and additional injections may be necessary. It is not recommended that pregnant women or nursing mothers receive Sculptra®. Sculptra® should not be injected close to any permanent implants. I understand that the following are among the expected side effects of the Sculptra® procedure:

### **Bleeding and Bruising:**

It is possible, though unusual, to have a bleeding episode from a filler 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 filler injections.

**Pain, Swelling, and Redness:**

Swelling is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary. Discomfort associated with injections is normal and usually of short duration. Redness may occur after injection and be present for a few days. Visible needle marks from the injections occur normally and resolve in a few days.

**Skin Reactions:**

Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days. Skin rash, itching, and tenderness may occur following injections. After treatment, you should minimize exposure to excessive sun or UV lamp exposure and extreme heat for 24 hours after treatment. If you are considering laser treatment, chemical skin peeling, or any other procedures after injection or you have recently had such treatment, there is a possible risk of an inflammatory reaction at the injection site.

**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 filler injections. There can be a variation from one side to the other in terms of the response to the injection. Addressing this may require additional injections to the same or nearby areas, however, in some cases, this uneven appearance can persist for several weeks or months.

**Accidental Intra-Arterial Injection:**

It is extremely rare that during the course of injection, fillers 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 or vision abnormalities. These complications can also include stroke, temporary scabs, or permanent scarring of the skin. If you have changes in your vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin or unusual pain during or shortly after treatment, you should notify your healthcare practitioner immediately. The risk and consequences of accidental intravascular injection of fillers is unknown and not predictable. 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, and cause unacceptable scarring.

I acknowledge the following has been discussed with me:

- I understand what my medical provider can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
- I understand that multiple treatments are necessary to achieve desired results. Treatments generally last up to 2 years but the effect can be shorter or longer. Most areas of treatment will require 2 to 4 sessions, usually at 4- to 6-week intervals for optimal correction. Because individual responses to Sculptra® may vary, the exact number of treatment sessions required cannot be predicted with complete accuracy. Maintenance treatments may be necessary to maintain desired results with evaluation after 18-24 months. No guarantee, warranty, or assurance has been made to me as to the results that may be obtained. Clinical results will vary per patient. I agree to adhere to all safety precautions and regulations during the treatment.
- After each injection session, tissue volume in the treated area will gradually build up over the following weeks and months as the body produces new collagen. At the time of my next session of Sculptra®, my response to the previous treatment will be assessed and additional treatments can be performed if needed to optimize my correction.
- I understand that Sculptra® does not treat the underlying cause of tissue or fat loss; rather it is meant to improve the appearance of the affected area(s).
- I understand and agree that all services rendered to me are charged directly to me and that 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 this be required. No refunds will be given for treatments received.
- I have read and understand the Pre- and Post-Treatment Instructions. I agree to follow these instructions carefully. I understand that compliance with recommended pre- and post-procedure guidelines is crucial for healing, and prevention of side effects and complications as listed above.

- I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures.
- For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
- I attest that I am not aware that I am pregnant. I am not breastfeeding. I do not have any significant medical disease.

**For women of childbearing age:** By signing below I confirm that I am not pregnant and do not intend to become pregnant at any time during the course of the treatment. Furthermore, I agree to keep Honey Skincare Studio and my provider informed should I become pregnant during the course of the treatment.

## WRITTEN CONSENT

Photographic documentation will be taken. I hereby do authorize the use of my photographs for teaching purposes.

BY MY SIGNATURE BELOW, I ACKNOWLEDGE THAT I HAVE READ AND FULLY UNDERSTAND THE CONTENTS OF THIS INFORMED CONSENT FORM. I HAVE BEEN GIVEN THE OPPORTUNITY TO HAVE ALL MY QUESTIONS ANSWERED TO MY SATISFACTION BY HONEY SKINCARE HEALTHCARE TEAM.

I have read this form and understand it, and I request the performance of the procedure.

PRINTED NAME:

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SIGNATURE:

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DATE:

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