

## **CHARLOTTESVILLE DERMATOLOGY PLC**

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### **INFORMED CONSENT FOR SCULPTRA® THERAPY**

Sculptra® therapy is the injection into the skin and underlying tissues of poly-L-lactic acid. Sculptra® therapy is designed to help correct skin depressions, such as creases, wrinkles, folds, scars, hollow eye rings, degenerative skin aging and loss of volume or facial lipoatrophy (loss of fat).

Sculptra® is a poly-L-lactic acid implant in the form of a sterile suspension. Poly-L-lactic acid is a biocompatible (does not harm the body), biodegradable (broken down or metabolized by the body) synthetic polymer from corn or vegetable sugar. Poly-L-lactic acid has been used medically for many years in dissolvable stitches, vaccines and medication; this does not require pretreatment skin testing for allergies.

My doctor has informed me that depending on the area and condition treated, the volume of Sculptra® used and the injection techniques, the effect of a treatment with Sculptra® may last 1 to 2 years, but in some cases the duration of the effect can be shorter or longer. Most areas of treatment will require 2 to 4 sessions, usually at 4-week intervals, for optimal correction. Because individual responses to Sculptra® therapy may vary, the exact number of treatment sessions required cannot be predicted with complete accuracy. Additionally, in order to maintain the desired degree of correction, intermittent "touchup" treatments may be needed.

After each injection session, tissue volume in the treated area will gradually build up over the following weeks and months as your body produces new collagen. At the time of your return visit for your next session of Sculptra® therapy, your response to the previous treatment will be assessed and additional treatments can be performed if needed and agreed upon to optimize your correction. Sculptra® therapy does not treat or cure the underlying cause or disease of tissue or fat loss; rather it is designed to improve the appearance of the affected area(s).

I have been educated on some of the features, benefits and possible risks involved with using Sculptra® and have had my questions answered to my satisfaction. Some of these possible risks include:

- After the injection(s) some common injection-related reactions could occur, although rare, swelling, redness, pain, itching, discoloration and tenderness at the injection site(s). These typically resolve spontaneously, usually within 1 to 15 days after injection(s).
- Because Sculptra® therapy injections are administered in a solution containing water, there will be an initial swelling (edema) that will be noticeable for at least several hours and perhaps as long as several days. This effect is temporary and does not affect the long-term tissue response.
- Small bumps under the skin, termed micro-nodules, which may be non-visible or visible, may be felt in the area(s) of treatment. Usually these bumps may only be felt when pressing on the skin. Micro-nodules typically last from 6 to 12 months and may spontaneously disappear. They usually do not require treatment and usually do not have any symptoms.

- Indurations, or a feeling of fullness or thickness, can be felt in the injection area(s). This is a normal response of the treated tissue to the process of inflammation and new collagen formation. Simply massaging the treated area(s) gently 3 to 5 times a day for 3 to 5 minutes for 3 to 5 days after the injection can help minimize indurations.
- Visible bumps may occur in rare instances, and they may be associated with redness, tenderness, skin discoloration or textural alteration. These bumps, which may be termed granulomas, may or may not require treatment, including but not limited to injections, freezing or excision.
- Other rarely reported adverse events include injection site abscess, allergic reaction, skin hypertrophy and/or atrophy, malaise, fatigue and edema.
- Sculptra® therapy is contraindicated (not allowed) in pregnancy or during breastfeeding. If you believe you may be pregnant or are breastfeeding, please inform the doctor prior to injection.

Initial \_\_\_\_\_

Sculptra® therapy has been approved by the U.S. Food and Drug Administration (FDA) for the restoration and/or correction of facial fat loss (lipoatrophy) in people with HIV. Sculptra® therapy has not been specifically approved by the FDA for aesthetic (cosmetic) use. Sculptra® therapy (New-Fill®) has been performed since 1999 in more than 150,000 patients in more than 30 countries, principally for cosmetic use. Treatment with Sculptra® for cosmetic and reconstructive use is allowed in the U.S. as an "off-label" indication.

The use of antiinflammatory drugs, anti-clotting agents or aspirin might cause bleeding or increased bruising at the injection site(s). If you have previously had facial herpes simplex at the injection site, the injection might provoke an outbreak. If any of these conditions apply to you, please inform our office.

Any injection, for any reason, carries a small risk of infection. If the needle accidentally punctures a blood vessel, this may result in bruising, temporary discoloration of the treated area, scabbing, shedding and/or shallow scarring.

Allergic reactions are rare. An allergic reaction can manifest itself by prolonged redness, itching, swelling or a hardening of the skin around the injection site(s). The reaction can last for as long as 3 to 4 months and in rare cases for more than a year. Please make sure you inform us of all known allergies and sensitivities.

Initial \_\_\_\_\_

The use of and indication for Sculptra® has been explained to me, and I have had the opportunity to have my questions answered to my satisfaction. My doctor has provided me with this informed consent, and I have been given the time and opportunity to review it with any other individuals of my choice.

I have received followup instructions, including followup appointments, which I must follow after receiving injections. I agree to follow the procedures and medical advice given.

I have been told that I can reasonably expect the foregoing benefits from Sculptra® but that no results can be guaranteed or assured and no such guarantees or assurances have been given to me. Additionally, I understand that the practice of medicine is not an exact science and positive outcomes cannot be guaranteed, nor can promises or guarantees be made regarding potential negative outcomes. I have had appropriate alternative treatment to Sculptra® therapy explained to me including other fillers, surgical procedures and topical treatments.

I have been informed that Sculptra® needs to be reconstituted or mixed/prepared prior to my appointment, and if I cancel with less than 24 hours notice prior to my appointment, I will be charged the full price of the vial. I agree to this financial policy.

Initial \_\_\_\_\_

By signing this informed consent, I agree to being treated with Sculptra® as described above. I acknowledge that I understand the procedures and the risks, and that it has been explained to me to my satisfaction, and I agree to hold all parties harmless from the described risks on the condition that the injection(s) of Sculptra® are administered in accordance with appropriate guidelines.

I have had the cost of Sculptra® therapy fully explained to me and agree to pay the following amount in accordance with the office policies of Charlottesville Dermatology PLC. Total \$ \_\_\_\_\_

Patient Name (print): \_\_\_\_\_ Chart #: \_\_\_\_\_

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(or Parent/Legal Guardian)

Witness: \_\_\_\_\_ Date: \_\_\_\_\_  
(Charlottesville Dermatology PLC Representative)

**PHOTOGRAPHIC RELEASE CONSENT:**

I give permission to Charlottesville Dermatology PLC to take photographs of my treatment areas for diagnostic purposes and to document for the medical record my response to Sculptra® therapy. I agree that these photographs are the property of Charlottesville Dermatology PLC.

I give my permission for Charlottesville Dermatology to use these photographs for teaching purposes, for use in scientific publication, books, journals, lectures, seminar and electronic media. It is understood that in any such publication I shall not be identified by name, and that appropriate measures shall be made to protect my identity. I understand that I will not receive any compensation for the use of my photographs for scientific and/or teaching/educational purposes.

\_\_\_\_\_  
Charlottesville Dermatology PLC Date

\_\_\_\_\_  
Patient/Guardian Signature Date