



## Sculptra Informed Consent for Treatment

Procedure: Sculptra is a poly-L-lactic implant in the form of a sterile apyrogenic suspension. Poly-L-lactic acid is a biocompatible (does not harm the body), biodegradable (broken down or metabolized by the body), synthetic polymer from the alphahydroxy- acid family (fruit acids). Poly-L-lactic acid has been used medically for many years in dissolvable stitches, and does not require pre-treatment skin testing allergies. Sculptra requires multiple sessions, generally 2-4 treatments spaced 3-6 weeks apart.

Sculptra is generally a safe procedure however possible side effects of these injections include but are not limited to:

- After the injection(s) some common injection- related probability will occur, these may include swelling redness, pain, itching, discoloration and tenderness at the injection site. These typically resolve spontaneously, usually within 1 to 15 days after the injection.
- Because Sculptra therapy injections are administered in a solution containing water, there will be initial swelling, (edema) that will be noticeable for at least several hours and perhaps as long as several days. The 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 areas of treatment. Micro- nodules typically last from 6-12 months, and may spontaneously disappear. They usually do not require treatment and usually do not have any symptoms.
- Induration, or a feeling of fullness or thickness can be felt in the injection area. This is a normal response to the treated tissue to the process of inflammation and neocollagenesis. Simply massage the treated areas gently 3 to 5 times per day for 3 to 5 minutes, for 3 to 5 days after the injection can help minimize induration.
- 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 breast feeding. If you believe you may be pregnant or are breastfeeding, please inform the provider prior to injection.
- Sculptra therapy has been approved by the United States Food and Drug Administration (FDA), for the restoration and/or correction of facial fat loss (lipoatrophy) in people with HIV. Treatment with Sculptra for cosmetic and reconstructive use is allowed in the US as an “off-label” indication.
- The use of anti-inflammatory drugs, anti-clotting agents or aspirin might cause bleeding or increase bruising at the injection site. If you’ve 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 your provider.
- Any injection, for any reason, carries a small risk of infection. If the needle accidentally punctures a blood vessel, this may result in discoloration of the treated area, scabbing, shedding and shallow scarring.
- Allergic reactions are rare. An allergic reaction can manifest itself by prolonged redness, itching, swelling or hardening of the skin around the injection site. Please make sure to inform us of all known allergies and sensitivities.
- 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. I have been given the time and opportunity to review this informed consent.

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I can reasonably expect the forgoing 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 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 treatments to Sculptra therapy explained to me including other fillers, surgical procedures and treatments.

I have been informed that Sculptra needs to be reconstituted (prepared) prior to my appointment. I understand that payment in full is expected one week prior to treatment and that if I cancel my appointment I will still be charged the full price of the treatment.

I give permission to take photographs of my treatment areas for diagnostic purposes and to document for the medical record response to Sculptra therapy. I agree that these photographs are the property of the doctor's office, and I give my permission to use these photographs for teaching purposes, for use in scientific publications, books, journals, lectures, seminars 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. Initial here if opting out of social media pictures. \_\_\_\_\_

By signing this consent form I am agreeing to be treated with Sculptra and have read the form in its entirety. I also release Megan Davies and Desert Holistic Health PLLC from any responsibility associated with the side effects mentioned above as well as any effects caused by my failure to adhere to proper aftercare instructions.

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Patient Signature

Date