

Informed Consent

Sculptra® Aesthetic Treatment

Overview: Sculptra® Aesthetic is an FDA approved injectable poly-L-lactic acid implant. Poly-L-lactic acid is a biocompatible, biodegradable, synthetic polymer. Poly-L-lactic acid has been used medically for many years in dissolvable sutures and does not require pre-treatment skin testing for allergies.

Sculptra® Aesthetic is injected into the skin and underlying tissues. It is designed to help correct skin depressions, such as wrinkles, folds, scars, degenerative skin, aging, and facial fat loss.

Procedure: Cleansers are used to prepare the site prior to injection. After the area is cleansed, Sculptra® Aesthetic is injected into the skin of the face using a fine tube called a microcannula, that is inserted into the skin after making a lead hole or "port" in the skin surface using a needle. This results in 4-10 injections into the skin of the face.

Anticipated Benefits/Duration of Action: Depending upon the area and condition treated, patient factors, the volume of Sculptra® Aesthetic used, and the injection technique, the effect of a treatment with Sculptra® Aesthetic may last from 1 to 2 years but the duration of 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® Aesthetic therapy may vary, the exact number of treatment sessions required may vary. In addition, to maintain the desired degree of correction, intermittent "touch-up" 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 the body produces new collagen. At the time of your next session of Sculptra® Aesthetic therapy, your response to the previous treatment will be assessed and additional treatments can be performed if needed to optimize your correction.

Sculptra® Aesthetic therapy does not treat the underlying cause of tissue or fat loss; rather it is meant to improve the appearance of the affected area(s).

Outcomes: Occasionally, despite proper planning, patients do not always respond as desired to Sculptra® Aesthetic therapy.

Risks and Complications: There are certain inherent and potential risks and side effects with any invasive procedure and such risks include but are not limited to:

1) Post-treatment discomfort, swelling, redness, discoloration, bruising;

- 2) Initial swelling will be noticeable for at least several hours and perhaps as long as several days;
- 3) Micronodules, which may be non-visible or visible, may be felt when palpating the skin. Micronodules typically last from 5 to 12 months and may spontaneously disappear. They usually do not require treatment, and usually do not elicit any symptoms;
- 4) Granulomas may occur in rare instances, and may be associated with redness, tenderness, skin discoloration, or textural alteration. These granulomas may or may not require further treatment;
- 5) A feeling of the skin thickening, or Induration, is a normal response of the treated tissue to the process of inflammation and formation of new collagen. Gentle massage of the treated areas can help minimize this;
- 6) Asymmetry;
- 7) Scarring;
- 8) Cold Sore eruption;
- 9) Allergic reaction;
- 10) Post---Treatment bacterial, viral, and/or fungal infection;
- 11) Rarely, injection site abscess, skin hypertrophy and/or atrophy, malaise, fatigue, and edema;
- 12) Injection into blood vessels with resulting tissue necrosis;
- 13) Treatment requiring further injectable therapy.

Disclosures: I attest that I am not aware that I am pregnant or breastfeeding; do not have any significant medical disease; do not have any severe allergies including any intolerance or anaphylaxis to previous dermal fillers; have not taken Accutane (Isotretinoin) within the last 12 months; do not have any bleeding disorder; do not have permanent implants close to the region to be injected.

Medications: I understand that the ingestion, within 1 week of treatment, of medications and supplements such as aspirin, anti-inflammatory medications, non---steroidal anti---inflammatory drugs (NSAIDs), steroids, anti---coagulants, vitamin A, vitamin E, Gingko Biloba, fish oil supplements, St. John's Wort, garlic, and flax seed oil may result in an increased and prolonged duration of bruising at or near the injection site.

Alternatives to wrinkle reduction therapy and volume enhancement with Sculptra® Aesthetic include chemical peels, laser resurfacing, treatment with Botox® Cosmetic, treatment with other dermal fillers, and surgical therapies.

Post---Treatment Instruction: Apply a cool compress to the injection site(s) for up to 48 hours. Avoid strenuous exercise for 24 hours post---treatment. Avoid excessive sun or heat exposure for 24 hours post---treatment Massage treated area gently 5 times per day for 5 minutes for 5 days after the injection.

Consent: I have read this Sculptra® Aesthetic Therapy Consent Form and understand it in its entirety. I have had the opportunity to ask questions to my treating provider which have been answered satisfactorily. I voluntarily consent to Sculptra® Aesthetic therapy treatment, and accept the risks and possible complications of this procedure. I am aware that no guarantees have been made regarding the results of this procedure. I understand that photographs may be taken before and/or following treatment and will be kept confidential and will become part of my medical record.

I give consent to have pre and post treatment digital photos taken to assess for treatment efficacy and monitor progress and for comparison to post treatment results if needed. These images will not be used for any other purpose.

X _____

Patient Signature and Date

X _____

Witness and Date