



Sculptra Aesthetic

Consent form

Name: _____ **Date:** _____

INTRODUCTION

This is an informed consent document, which has been prepared to help inform you about Sculptra Aesthetic. A natural, youthful face is full and not tight. Age related changes of the lips and mouth include atrophy of the lips and atrophy of the corners of the mouth resulting in downturn. Another early sign of aging is the development of nasolabial lines and hollow appearance to cheeks. Although the upper face can easily be rejuvenated with Botox/Dysport, the lower face is less amenable to this treatment. In order to treat the entire aging face, a combination of Botox/Dysport and injectable fillers is often needed for optimal results.

INDICATIONS AND PROCEDURE

Sculptra Aesthetic is a safe, synthetic, and biocompatible material that is injected below the surface of the skin. It's made up of microspheres (a spherical shell that is usually made of a biodegradable or resorbable plastic polymer, that has a very small diameter usually in the micrometer or nanometer range, and that is often filled with a substance, as a drug or antibody, for release as the shell is degraded) of poly-L-lactic acid. Because poly-L-lactic acid is the main ingredient in Sculptra Aesthetic, patients don't require allergy testing.

The results of Sculptra Aesthetic are not immediate. At your first treatment visit, it may appear that Sculptra worked immediately because of swelling from the injections and the water used to dilute Sculptra Aesthetic. A few days following the treatment, when the swelling goes down and the water is absorbed by your body, you may look as you did before your treatment. Sculptra Aesthetic takes time to gradually correct the depression in your skin. Your doctor will decide the appropriate number of treatment sessions and the amount of Sculptra Aesthetic you will need at each session. Multiple sessions are often required and patients with severe facial fat loss may require 3 to 6 treatment sessions.

- Sculptra Aesthetic is injected under your skin into the tissue with a very fine needle into the areas of the face.
- An anesthesia, numbing medicine used to reduce the discomfort of the injection, may or may not be used.
- The treatment site(s) is washed first with an antiseptic (cleansing) solution.
- The depth of the injection(s) will depend on the depth of the wrinkle(s) and its location(s). Multiple injections might be made depending on the site, depth of the wrinkle, and technique used.
- Following each injection, the injector may gently massage the correction site to conform to the contour of the surrounding tissues.
- If the treated area is swollen directly after the injection, ice may be applied on the site for a short period.

POTENTIAL RISKS

- Although a very thin needle is used, common injection-related reactions could occur. These include: some initial swelling, pain, itching, discoloration, bruising or tenderness at the injection site. You could experience increased bruising or bleeding at the injection site if you are using substances that reduce blood clotting such as aspirin or other non-steroidal anti-inflammatory drugs such as Advil, as well as vitamins and herbal products. These reactions generally lessen or disappear within a few days but may last for a week or longer.
- As with all injections, this procedure carries the risk of infection. The syringe is sterile and standard precautions associated with injectable materials have been taken.
- Some visible lumps may occur temporarily following the injection.
- Some patients may experience additional swelling or tenderness at the injection site and in rare occasions, pustules (blister) might form. These reactions might last for as long as approximately 2 weeks, and in appropriate cases may need to be treated with oral corticosteroids or other therapy. In rare cases (fewer than 1 in 15000) granuloma formation, superficial necrosis, and urticaria (hives) have been reported.
- Sculptra Aesthetic should not be used in areas other than the tissues of the face.

- Sculptra Aesthetic should not be used in patients who have experienced this hypersensitivity, those with severe allergies, or in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives).
- If you are considering laser treatment, chemical skin peeling or any other procedure based on a skin response after Sculptra Aesthetic treatment, or you have recently had such treatments and the skin has not healed completely, there is a possible risk of an inflammatory reaction at the implant site.
- Most patients are pleased with the results of Sculptra Aesthetic. However, like any cosmetic procedure, there is no guarantee that you will be completely satisfied. There is no guarantee that wrinkles and folds will disappear completely, or that you will not require additional treatments to achieve the results you seek.
- After treatment, you should minimize exposure of the treated area to excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away.
- If you are prone to cold sores/fever blisters, additional measures may be necessary to prevent a break out - please notify Dr. Pisarski and staff if you have a history of cold sores/fever blisters.

ALTERNATIVES

This is strictly a voluntary cosmetic procedure. No treatment is necessary or required. As explained, not all wrinkles will respond to soft Sculptra Aesthetic™. Other alternatives are dermabrasion; chemical peeling; laser resurfacing; face-lifting, browlifting, necklifting, and other surgical resecting of the frown muscles of the frown muscles of the brow; treatments with Retin-A or Renova or alpha hydroxy acids may also produce some benefits.

The practice of medicine and surgery is not an exact science, and, therefore, reputable practitioners cannot guarantee results. The results of the injections may not last for as long or as well as expected. There are no promises or guarantees regarding the degree of improvement when using Sculptra Aesthetic.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed treatment along with disclosure of risk and alternative forms of treatment. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all inclusive in defining other methods of care and risk encountered. Your physician may provide you with additional or different information that is based on all the facts in your particular case and the state of medical knowledge at the time.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to changes as scientific knowledge and technology advance and as practice patterns evolve. It is important that you read the above information carefully and have all of your questions answered before signing the consent statement.

CONSENT

I understand that my consent and authorization for this procedure is strictly voluntary. By signing this informed consent form, I hereby grant authority to Dr. Pisarski to inject Sculptra Aesthetic. The nature and purpose of this procedure, with possible alternative methods of treatment as well as complications, have been fully explained to my satisfaction. No guarantee has been given by anyone as to the results that may be obtained by this treatment.

I have read this informed consent and certify that I understand its contents in full. I have had enough time to consider the information from my physician and feel that I am sufficiently advised to consent to this procedure.

If pre/post-operative photos are taken of the treatment for record purposes, I understand that these photos will be the property of Dr Pisarski. I consent to the photographing of the procedure for medical, scientific or educational purposes provided the pictures do not reveal my identity. For purposes of education, I consent to the admittance of observers during the procedure.

I have also been given specific follow-up instructions and will comply with these. I agree to follow up with my Dr. Pisarski following my treatment and at reasonable intervals to assess my status. I agree to inform Dr. Pisarski of any problem that I am having and to allow him to see me at that time. If second opinions or consultants are recommended to me, I plan to follow her suggestions.

I certify that I have read and understand this consent and that all blanks were filled in prior to my signature.

Signature - Patient

Print Name

Date

Signature - Witness

Print Name/Title

Date

Signature – Physician

Gregory P. Pisarski, MD
Print Name/Title

Date