Consent Form for Sculptra Treatment

This is a patient consent form for treatment using Sculptra. Please read it carefully before signing.

This disclosure is not meant to alarm you; it is simply an effort to better inform you. Being informed will help you make the decision whether to undergo treatment.

What is Sculptra? Sculptra is a sterile, injectable, biocompatible, biodegradable material that is made of very small particles of a synthetic polymer named "poly-L-lactic acid" (PLLA), carboxymethylcellulose, non-pyrogenic mannitol and sterile water.

Indications for Treatment: Sculptra has been approved by the FDA for the following indications:

- Correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles for use in immune-competent subjects
- Correction of fine lines and wrinkles in the cheek region for use in immune-competent subjects
- For restoration and/or correction of signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus

These are the "on-label" uses for Sculptra. Sculptra is also used "off-label" for the correction of facial volume loss using injections to the temples, cheeks, and lower face. Other facial and body cosmetic corrections are also possible. It is also used off-label on the neck, chest, abdomen, buttocks, arms, and above the knees. The safety and effectiveness of treating face and body areas "off-label" has not been approved or studied by the FDA; however, Sculptra has been extensively used in most areas of the face and many parts of the body. Dilution and hydration time as well as injection technique may vary. The safety and effectiveness of injecting Sculptra in larger amounts, different frequencies, at anatomic sites different than the deep dermis of the nasolabial folds, with different techniques, and at anatomic sites with previous dermal filler injections have not been evaluated by the FDA.

Alternatives to treatment: There are alternatives to Sculptra treatment, including no treatment at all, fat injections, or other facial soft tissue augmentation or implants, hyaluronic acid based fillers like Restylane and Juvederm, neurotoxins like Botox and Dysport, laser skin resurfacing, chemical peels, cosmeceuticals or plastic surgery for wrinkle reduction, correction of volume loss, and improvement in skin quality.

Results: The actual degree of improvement cannot be predicted or guaranteed. Furthermore, the effect will gradually wear off and additional treatments are necessary to maintain the desired effect. Results depend on the number of treatment sessions, the amount of Sculptra used per treatment session, the dilution, as well as the injection technique. Using multiple vials often results in more dramatic improvement of wrinkles and volume loss. The patient is responsible for the cost of each vial and treatment without any guarantee of results.

Side effects and complications include but are not limited to:

Potential allergic reaction. As with any product, allergies can develop during or after injection. Patients with known hypersensitivity to Sculptra or any of its components or certain numbing medications, such as lidocaine, should avoid these injections.

Injection site and other reactions: Subcutaneous papules and nodules, hematoma, bruising-ecchymosis, bleeding, edema (swelling), discomfort, inflammation, and erythema (redness) can occur. The subcutaneous papules and nodules are usually confined to the injection site, typically palpable and can occur days to months after injection and may have a prolonged time course to resolution. In rare cases, nodules may need to be surgically excised with the associated risks of surgery. Discoloration, induration, hypertrophic and keloid scars, itching, pain, nerve damage, over-correction, granulomas, tenderness, swelling, and asymmetry can also occur. As with all transcutaneous procedures, Sculptra carries a risk of infection.

One of the serious risks with Sculptra treatment is unintentional injection into a blood vessel. The chances of this happening are small, but if it does happen, complications can be serious, and may be permanent. These complications include vision abnormalities, ophthalmoplegia (paralysis of muscles that control eye movement), ptosis (droopy eyelid), **blindness**, **stroke**, and skin changes including necrosis and permanent scarring of the skin.

A 2015 publication by Beleznay et al showed 98 published cases of filler-related visual compromise reported in the medical literature between 1906 and 2015. A follow up paper by the same team published in 2019 showed a further 48 published cases from January 2015 through September 2018 bringing the total number of cases of filler related visual compromise reported in the medical literature up to 146 cases. Although the reported incidence is still small, the rate appears to be increasing and is probably underreported.

Certain parts of the face, such as the nose, glabella (between the eyebrows), forehead, and nasolabial folds are associated with a higher risk of vascular occlusion given vascular anatomy although occlusion can occur with any filler injection including on any of the other parts of the face or body.

While hyaluronic acid based fillers maybe dissolved using hyaluronidase, there is no consistent dissolving agent for Sculptra at this time.

If you experience changes in your vision, nausea, vomiting, signs of a stroke (including difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance or blanching of the skin, or unusual pain during or shortly after treatment, you should notify Dr. Patel immediately.

Injection of any filler material including Sculptra, particularly into the lip area and around the mouth, could trigger a recurrence of herpes (fever blisters, cold sores, shingles) and this outbreak maybe severe in nature. This could lead in some cases to scarring. Please disclose any medical history, including prior herpes outbreaks, to your treating physician.

Further treatment for additional improvement, or correction of side effects or complications may be necessary. When required, depending on event, treatments may include massage/manipulation, warm compress, corticosteroids, antibiotics, antihistamines, NSAIDs, aspiration/drainage of the production, saline injections and surgery. I understand I may be responsible for all such cost.

I understand that most humans have facial asymmetry and therefore perfect symmetry is unrealistic in most cases.

The risk of bruising or bleeding may be increased by medications with anticoagulant effects, such as aspirin, non-steroidal anti-inflammatory drugs (e.g. Ibuprofen, Aleve, Motrin, Celebrex, etc), high doses of Vitamin E, and certain herbal supplements and foods (Ginkgo Biloba, St. John's Wart, Flaxseed, nuts, fish oil, Omega-3, etc).

The safety of Sculptra in pregnant or breast-feeding women has not been established and is therefore not recommended for these women.

Local anesthesia may be used to reduce the discomfort of the procedure including the topical application of anesthetic cream or ointment and/or injections of anesthetic for a nerve block or local infiltrative anesthesia.

By signing below, you consent that you have read the above consent, understand it, and have had the risks, benefits, and alternatives explained to you, and have had the opportunity to ask questions and refuse treatment. You have chosen this treatment voluntarily and no guarantees about results have been made. Further treatments may be needed. To the best of your knowledge, you are not pregnant or breastfeeding and do not have an allergy to lidocaine or any of the components of Sculptra. You give informed consent for Sculptra injections today as well as future treatments as needed by Dr. Shaun Patel. Further information is available upon request.

Patient signature _____

Date: _____

Witness signature _____

Date: _____