

# Sculptra® Informed Consent

Sculptra is a sterile suspension of injectable Poly-L-lactic acid (PLLA) and is indicated for use in people with healthy immune systems for the correction of shallow to deep skin contour deficiencies, fine lines and wrinkles in the cheek region, and smile lines. Unlike HA fillers that mainly work to fill lines and wrinkles, Sculptra works by primarily stimulating the skin's own natural collagen production over time to correct the appearance of facial lines, folds and wrinkles.

Your natural collagen is restored gradually, with results as soon as 1 month and sustained for up to 2 years. Typical treatment is 3 sessions spaced 3-4 weeks apart.

#### **Contraindications**

Sculptra should not be used by anyone that is allergic to any ingredients of the product (poly-L-lactic acid, sodium carboxymethylcellulose, non-pyrogenic mannitol, sterile water for injection) or have a history of **keloid formation** or **hypertrophic scarring. Safety has not been established in patients who are pregnant, lactating, breastfeeding, or under 18 years of age.** 

I am not aware that I am pregnant. I am not lactating or breastfeeding. I do not have a history of keloid formation or hypertrophic scarring. Initial

Sculptra cannot be administered if you have had any vaccines, immunizations, antibiotics, steroids, procedures (including dental procedures and cleaning) or illnesses in the past 2 weeks.

I have not had any of the above treatments within the past 2 weeks. Initial

Inform your provider if you have a history of Herpes Simplex (cold sores) one week prior to your appointment.

## **Possible Risks and Precautions:**

One of the risk factors with using this product is unintentional injection into a blood vessel. The chance of this happening is very small, but if it does happen, the complications can be serious, and may be permanent. These complications can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin. If you have changes in vision, signs of a stroke (including sudden difficulty breathing, numbness or weakness in your face, arms or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin or unusual pain during or shortly after the treatment, you should notify your health care provider immediately. Initial

#### **Possible Risks and Discomfort**

You have been informed of some of the features, benefits, and possible risks involved with Sculptra and have had your questions answered to satisfaction. Some possible risks include:

- 1. Injection site swelling, tenderness, redness, pain, bruising, bleeding, and itching which typically resolves after 14 days.
- 2. Small lumps under the skin that are sometimes noticeable when pressing on the treated area. These micro-nodules tend to occur within the first 6-12 months after treatment. They usually do not require treatment or have any symptoms.
- 3. Larger lumps, some with delayed onset with or without inflammation or skin discoloration.
- 4. Sculptra is injected in a solution containing sterile water, so you may notice immediate fullness. These results are normal and temporary as it can take a few days for the water to full absorb.
- 5. Induration, or a feeling of fullness or thickness, can be felt in the injection areas. This is a normal response of the treated tissue to the process of inflammation and new collagen formation. Massaging the treated areas gently 5 times a day for 5 minutes for 5 days can help minimize induration.
- 6. The use of anti-inflammatory drugs, anti-clotting agents or aspirin might cause bleeding or increased bruising at the injection site.

## Initial\_\_\_\_\_

# Pre-Care

Unless prescribed by a physician, avoid Aspirin, Ibuprofen, Advil, Aleve, St. John's Wort, Vitamin D and E, garlic, Fish Oil/Omega 3, Flaxseed Oil, Omega's, Turmeric, Green Tea, Horse chestnut Seed Extract, Alcohol, and non-steroidal anti-inflammatory drugs (NSAIDS) in the 5-7 days prior to your treatment as they may promote the risk of bruising in the injection area.

If you are currently taking anti-coagulation medications (Warfarin, Coumadin, Heparin, Lovenox, Enoxaparin, Lepirudin, Refludan, Ticlopidine Ticlid, Clopidogrel, Plavix, Tirofiban, Aggrastat, Eptifibatide, Integrilin), discuss the use of these medications with your healthcare provider prior to your treatment.

If you are prone to cold sores (oral herpes simplex), take your prescribed medication (Famvir, Famciclovir, Valtrex, Valacyclovir, Acyclovir) as prescribed in the 24 hours prior to your treatment.

## **Post-Care**

You may experience redness, tenderness or swelling around the injected sites which should resolve over the next hours to days. Ice packs may be applied to help reduce swelling.

Bruising may be visible immediately or become apparent within a few days. Arnicare® gel will be applied topically during your treatment to reduce bruising. You may apply Arnicare® gel every few hours at home to help treat bruising. Please allow 7-14 days for bruising to heal.

Asymmetry is part of normal human anatomy and is often enhanced during times of swelling. Please allow 2 weeks for your Sculptra treatment to "settle".

Massage is a very important part of Sculptra aftercare. It ensures even distribution of the product into the tissue and allows collagen production to occur evenly and not in clumps. Massage in a circular motion with clean hands.

## 5-5-5: Massage the treated areas for 5 minutes, 5 times per day, for 5 days after your treatment

- Always wash your hands thoroughly before touching your face.
- Massage the treated areas for 5 minutes, 5 times a day for 5 days.
- Within the first 24 hours, apply an ice pack or ice wrapped in a cloth (avoid putting ice directly on your skin) to the treatment area to help reduce swelling.
- You may apply makeup a few hours after your Sculptra treatment if no complications are present. Please use clean makeup brushes to avoid infection.
- Avoid sun and UV sunlamp exposure until swelling and redness have disappeared.

You should notice gradual results over the next several weeks. Typical treatment plan is 3 sessions spaced 3-4 weeks apart. Results should continue to improve after each session.

Please make sure to schedule a 2 week follow up appointment.

The most common side effects include injection site swelling, tenderness, redness, pain, bruising, bleeding, itching and lumps.

Other side effects may include small lumps under the skin that are sometimes noticeable when pressing on the treated area. Larger lumps, some with delayed onset with or without inflammation or skin discoloration have been reported. Temporary lumps and/or bumps will resolve with time and typically not a cause for concern.

#### Please report any worsening or prolonged symptoms.

#### **Results**

I understand this is an elective procedure and I hereby voluntarily consent to treatment for facial rejuvenation, establish proper lip and smile lines, and replacing facial volume. The procedure has been fully explained to me. I have read the above and understand it. My questions have been answered satisfactorily. I accept the risks and complications of the procedure and understand that no guarantees are implied as the outcome of the procedure. I also certify that if I have any changes in my medical history, I will notify the healthcare provider at BloGo Salon + MedSpa immediately. I consent to this treatment today and for all subsequent treatments. I am over the FDA approved age or have signed a waiver.

#### **Publicity Materials**

I authorize the taking of clinical photographs and videos and their use for scientific and marketing purposes. I hold BloGo Salon + MedSpa and Dr Justin Bevel harmless for any liability resulting from this production. I waive my rights to any royalties, fees and to inspect the finished production as well as advertising materials in conjunction with these photographs. Initial\_\_\_\_\_

## Payment

I understand that this is an "elective" procedure, and that the payment is my responsibility and is expected at the time of treatment.

#### **Questions or concerns:**

Please contact us at (205) 861-2546

For questions or concerns not requiring an immediate response please email: <a href="mailto:shannon@blogosalonmedspa.com">shannon@blogosalonmedspa.com</a>

If you are experiencing a medical emergency, please call 911 promptly.

Patient Name: \_\_\_\_\_

Date of Birth: \_\_\_\_\_

Patient Signature\_\_\_\_\_

Date: \_\_\_\_\_