

Information and Consent: Sculptra™ Therapy

Practice/Physician Name: _____

Sculptra™ is a cosmetic product used to fill defects of the skin at deep levels. It is important that you understand that Sculptra™ is simply a collagen simulator. The Sculptra™ product itself is NOT providing the filling action...the Sculptra™ product causes a reaction in the skin, which forms new collagen. The Sculptra™ product itself is digested by the skin and is gone about 2 years after a treatment, but the new collagen layer which is left behind may last 2 or more years. Sculptra™ requires a SERIES of treatments to achieve adequate filling for most skin defects. You may need anywhere from 2 to 6 treatments at 4 to 8 week intervals to achieve your best result.

Sculptra™ was just approved for U.S. by the FDA in August 2004, initially only for the treatment of HIV-related facial fat loss. U.S. general cosmetic use of Sculptra™ is considered "off-label" use. The doctor will discuss if this product is appropriate for you.

What you can expect:

- 1) The doctor will take an abbreviated medical history from you before your first treatment, as well as take photographs of your treatment area. It is your duty to disclose to the doctor your complete medication list, and any pertinent medical history, particularly of bleeding disorders, previous cosmetic surgical procedures, keloid scar history, history of facial herpes, and use of aspirin, anti-inflammatory, anticoagulant, or immune suppressive therapies. **Stop all aspirin, ibuprofen/Motrin, Aleve, and Vitamin E (pills) for 1 week prior to treatment.**
- 2) Sculptra™ is injected under the skin in the area to be treated (usually the face) using several injections per area. These injections are mildly painful. The treated areas will be mildly sore for up to 3 days after treatment.
- 3) Your skin will be deeply massaged/manipulated by the doctor after treatment, and then ice packs applied for several minutes. This helps to minimize bruising. You may resume normal activity immediately.
- 4) Your skin may appear "lumpy" and mildly red or swollen for 24 to 48 hours after the treatment. This is normal. There may be mild bruising of the skin, especially if treatment is around the eyes, which may last for up to 7 days. If swelling is severe, pain or bruising is increasing, or fever develops, call the doctor.
- 5) You will have puffiness (not severe) for up to 10 days after the procedure. **This is simply the water used to carry the Sculptra™ product into your skin, and most of this is reabsorbed within the first week.**
- 6) Treatment sessions are generally spaced 4 to 8 weeks apart. Deep defects may require 4 to 6 treatment sessions; persons with lesser skin defects can often be treated with as little as 2 sessions. The volume of Sculptra™ injected at each session is entirely dependent on the size of the defect being corrected. Single treatments every 1 to 3 years appear to "keep up" with the natural loss of tissue volume due to aging.
- 7) **The effect of Sculptra™ is slow and gradual** as your skin forms collagen around the product crystals. **Your best results are seen about 3 months after your last treatment. Please be patient!**

Possible adverse events;

- 1) Swelling and bruising as noted above. Temporary numbness or tingling in the treated area or temporary partial facial muscle paralysis (from the lidocaine anesthetic), lasting less than 2 hours.
- 2) Infection at the injection sites. This would be very rare and treated with routine antibiotics.
- 3) Undesired cosmetic effect, such as unexpected appearance after treatment. These events can be limited by clear communication with the doctor about your specific treatment goals.
- 4) Small "bumps" commonly form deep in the skin in the treated areas. This represents new collagen which has formed deep in the skin. These have been reported to last for an indefinite period of time.

After each treatment, please avoid the sun for 48 hours and deeply massage the treated area each night for 7 days.

Your signature below indicates that you have read the above and consent to Sculptra™ treatment. If any information regarding Sculptra™ becomes available which may affect your willingness to continue with treatments, you will be informed by the doctor. The full cost associated with Sculptra™ administration falls entirely upon the patient. A copy of this signed consent form will be given to you.

Signature: _____ Patient Name: _____ Date: _____

Signature: _____ Witness Name: _____