

## SCULPTRA INFORMED CONSENT

### *Reverza Aesthetics*

Sculptra is a sterile suspension of Poly-L-Lactic acid, which is a biocompatible (does not harm the body), synthetic polymer from the alpha-hydroxy acid family (fruit acids). Poly-L-Lactic acid has been used medically for many years in dissolvable stitches. Sculptra is designed to help correct skin depression, such as creases, wrinkles, folds, scars, hollow eye rings, skin aging, and facial lip-atrophy (loss of fat).

Sculptra has been used since 1999 in more than 150,000 patients in more than 30 countries, primarily for cosmetic use. Reverza staff has informed you that, depending on the area and condition treated, the volume of Sculptra used in the injection, the effect of a treatment with Sculptra may last from 1 to 2 years, but that in some cases the duration of the effect can be shorter or longer. Most areas of treatment will require multiple sessions at 4 week intervals, for optimal correction. Because individual response to Sculptra may vary, the exact number of treatments sessions required cannot be predicted with complete accuracy. Additionally, in order to maintain the desired degree of correction, intermittent "touch-up" treatments may be needed.

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

1. After the injection(s), some common injection-related reactions probably will occur. These may include swelling, redness, pain, itching, discoloration and tenderness at the injection site. These typically resolve spontaneously, usually within 1 to 15 days after injection.
2. Because Sculptra is injected in a solution containing water, there will be an initial swelling (edema) that will be noticeable for at least several hours and perhaps as long as several days. This effect is temporary and does not affect the long-term tissue response.
3. 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. Simply massaging the treated areas gently 5 times per day for 5 minutes after the injection can help minimize induration.
4. One possible delayed side effect is small bumps under the skin, termed micro-nodules, which may be non-visible or visible and may be felt in the areas of treatment. Usually these bumps may only be felt when pressing on the skin. Micro-nodules tend to occur within the first 6 to 12 months after the treatment. They usually do not require treatment and usually do not have any symptoms.
5. Visible bumps may occur in rare instances and they be associated with redness, tenderness, skin discoloration or textural alteration. These bumps, which may be termed granuloma, may or may not require treatment, including, but not limited to, injection, freezing or excision.
6. Other rarely reported adverse events include: injection site abscess, allergic reaction, skin hypertrophy (exaggerated reduction of collagen and tissue elasticity) and/or atrophy (reduction of collagen and tissue elasticity) and swelling (edema).
7. The use of anti-inflammatory drugs, anti-clotting agents or aspirin might cause bleeding or increased bruising at the injection site.

I understand that this is an elective procedure and that I hereby voluntarily consent to treatment for facial rejuvenation and replacement of 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 I understand that no guarantees are implied as to the outcome of the procedure. I agree to having before and after photos taken for the medical records. I also certify that if I have any changes in my medical history I will notify Reverza Aesthetics immediately.

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

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

Physician Signature \_\_\_\_\_

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