ATLANTIC
Oral Surgery & Facial Reconstruction Centres

Sculptra Consent Form
Injectable Poly-L-Latic Acid

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, and does not require pre-treatment skin testing for allergies.

Sculptra requires the injection into the skin and underlying tissues of Poly-L-Lactic acid. Sculptra is designed to help correct skin depressions, such as creases, wrinkles, folds, scars, hollow eye rings, skin aging, and facial lipo-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. In Canada, Sculptra has recently been approved for aesthetic medicine and reconstructive use.

Your surgeon has informed you that depending on the area and condition treated, the volume of Sculptra used, the injection, the effect of a treatment with Sculptra may last up 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, usually 3 sessions at a minimal of 4 week intervals, for optimal correction. Because individual response to Sculptra may vary, the exact number of treatment 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.

Risks and Discomforts
You 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:

- 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.
- Because Sculptra is injectable 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.
- 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 for 5 days after the injection can help minimize induration.
- 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 happen within the first 6 to 12 months after the treatment. They usually do not require treatment, and usually do not have any symptoms.
- Visible bumps may occur in rare instances, and they may be associated with redness, tenderness, skin discoloration or textural alteration. These bumps, which may be termed granulomas, may or may not require treatment, including, but not limited to, injection, freezing or excision.
- Other rarely reported adverse events include: injection site abscess, allergic reaction, skin hypertrophy (exaggerated augmentation of collagen and tissue elasticity) and/or atrophy (reduction of collagen and tissue elasticity), malaise, fatigue and swelling (edema).
- The use of anti-inflammatory drugs, anti-clotting agents or aspirin might cause bleeding or increased bruising at the injection site.
- Any injection, for any reason, carries a small risk of infection. If the needle accidentally punctures a blood vessel, this may result in temporary discoloration of the treated area, scabbing, shedding and shallow scarring.
- Allergic reactions are rare, an allergic reaction can manifest itself by prolonged redness, itching, swelling or a hardening of the skin around the injection site. The reaction can last for as long as 3 to 4 months and in rare cases, more than a year. Please make sure you inform your surgeon of all known allergies and sensitivities.

It is important that you tell your surgeon about any health problems, medications and surgeon visits you have had in the past few months or at the present time. If you have previously been diagnosed with facial herpes simplex please inform your surgeon.

In the event that you experience any adverse reaction(s) to the Poly-L-Latic acid (Sculptra), you should immediately contact your surgeon.

You give permission to Dr. Bourget to take photographs of your face before treatment with Sculptra, upon the first treatment and at all other session visits for diagnostic purposes and for documenting your response to Sculptra.

You acknowledge that these photographs are the property of Dr. Bourget and give your permission to Dr. Bourget to use these photographs in scientific publications, for teaching/education purposes, in publications, books and journals. It is understood that for any such use, you will not be identifiable, and that appropriate measures will be taken to protect your identity. You understand that you will not receive any compensation for any use of the photographs.

If you have any further questions about Sculptra or did not understand any of the technical language, you should ask your surgeon before you sign this Informed Consent Form. If you would like more time to think about your decision to undergo treatment, you should not sign this Informed Consent Form and tell your surgeon.

By signing the Informed consent Form, you are agreeing to receive Sculptra. This Informed Consent Form has two (2) pages and by signing, you are indicating that you have read all these pages.

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Patient's Signature Date: