

Instruction Leaflet

SCULPTRA®

poly-L-lactic acid

DEVICE DESCRIPTION

SCULPTRA is an injectable implant that contains microparticles of poly-L-lactic acid, a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family. **SCULPTRA** is reconstituted prior to use by the addition of Sterile Water for Injection (SWFI), USP to form a sterile non-pyrogenic suspension.

COMPOSITION OF SCULPTRA

Each vial contains:

- Poly-L-lactic acid
- Sodium carboxymethylcellulose
- Non-pyrogenic mannitol

INDICATIONS FOR USE

SCULPTRA is suitable for increasing the volume of depressed areas, particularly to correct skin depressions, such as in skin creases, wrinkles, folds, scars and for skin aging.

SCULPTRA is also suitable for large volume or corrections of the signs of facial fat loss (lipoatrophy).

Injection techniques: The depth of injection and quantity of **SCULPTRA** used depend on the area to be treated and the result expected.

Over-corrections should be avoided, but if they occur, the area concerned should be thoroughly massaged to ensure proper distribution of the product. Limited correction of the treatment area allows for the gradual improvement of the depressed area over several weeks as the treatment effect occurs.

See “**INSTRUCTIONS FOR USE**” section for additional information.

CONTRAINDICATIONS

- **SCULPTRA** should not be used in any person who has hypersensitivity to any of the components of the product.

WARNINGS

- Use of **SCULPTRA** in any person with active skin inflammation or infection in or near the treatment area should be deferred until the inflammatory or infectious process has been controlled.
- Do not overcorrect (overfill) a contour deficiency because the depression should gradually improve within several weeks as the treatment effect of **SCULPTRA** occurs (see **INSTRUCTIONS FOR USE**).

- Injection procedure reactions to **SCULPTRA** have been observed consisting mainly of hematoma, bruising, edema, discomfort, inflammation, and erythema. The most common device related adverse effect was the delayed occurrence of subcutaneous papules, which were confined to the injection site and were typically palpable, asymptomatic and non-visible. Refer to **SIDE EFFECTS OF THE TREATMENT** for details.
- Special care should be taken to avoid injection into the blood vessels. An introduction into the vasculature may occlude the vessels and could cause skin infarction or embolism.
- Do not inject into the red area of the lip (vermillion). The long term efficacy and safety of Sculptra has not been established in the red area of the lip.

PRECAUTIONS

- **SCULPTRA** should only be used by health care providers with expertise in the correction of volume deficiencies after fully familiarizing themselves with the product, the product educational materials, and the entire instruction leaflet.
- **SCULPTRA** vials are for single patient use only. Do not reuse or resterilize the vial. Do not use if package or vial is opened or damaged.
- Long-term safety and effectiveness of **SCULPTRA** beyond two years have not been studied in controlled clinical trials.
- **SCULPTRA** should be used in the deep dermis or subcutaneous layer. Avoid superficial injections in order to avoid the appearance of early papules or nodules at the injection site, which could be suggestive of improper injection techniques (superficial placement, excessive amount of product, incorrect reconstitution) In addition massaging the treatment area to ensure proper distribution of the product may also minimize the appearance of papules or nodules.
- Special care must be taken when using **SCULPTRA** in areas of thin skin, such as the periorbital area. An increased risk of papules and nodules in the periorbital area has been reported (see section “**SIDE EFFECTS OF THE TREATMENT**”). Refer to **INSTRUCTIONS FOR USE** regarding injection techniques.
- As with all transcutaneous procedures, **SCULPTRA** injection carries a risk of infection. Standard precautions associated with injectable materials should be followed.
- As with all injections, patients treated with anti-coagulants may run the risk of a hematoma or localized bleeding at the injection site.
- The safety of **SCULPTRA** for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established.
- No studies of interactions of **SCULPTRA** with drugs or other substances or implants have been made.
- The safety of using **SCULPTRA** in patients with increased susceptibility to keloid formation and hypertrophic scarring has not been established.
- The patient should be informed that he or she should minimize exposure of the treatment area to excessive sun and avoid UV lamp exposure until any initial swelling and redness has resolved.

SIDE EFFECTS OF THE TREATMENT

The side effects usually resulting from the injections are transient bleeding from an area the size of the point of the needle or transient pain, localized redness at the injection site, ecchymosis, hematoma. Based on data obtained through post-marketing surveillance and clinical studies, nodules have also been reported. Subcutaneous papules invisible but palpable, or visible nodules including periorbital nodules or areas of induration have been noted in the injection area and may be due to over-correction. Nodules are occasionally associated with inflammation or discoloration.

The early occurrence of subcutaneous nodules may be minimized by adhering to proper dilution and injection technique (e.g., avoiding superficial injections or over-correction). In addition, massaging the treatment area to ensure proper distribution of the product may also minimize the appearance of nodules. Other rarely reported adverse events include injection site abscess, injection site infection including cellulites (facial), staphylococcal infection local infection, late granuloma formation, allergic reaction, injection site urticaria, skin hypertrophy and injection site atrophy, angioedema, telangiectasis, skin sarcoidosis. For nodule areas or late granuloma formation, the treatment may include multiple intralesional injections of corticosteroids or other such agents or elective excision.

ANY SIDE EFFECTS OR PRODUCT COMPLAINTS SHOULD BE NOTIFIED TO THE CORRESPONDING ADDRESS:

Sanofi-aventis Canada Inc.
2150 St. Elzear Blvd. West
Laval, Quebec, H7L 4A8
☎ 1-888-285-7872

INSTRUCTIONS FOR USE

The following supplies are used with **SCULPTRA** and are to be provided by the end-user:

- Sterile Water for Injection (SWFI), USP
- Single-use 5 mL sterile syringe
- Single-use 1-3 mL (depending on physician practitioner preference) sterile syringes (at least 2)
- 18 G sterile needles (at least 2)
- 26 G sterile needles (several should be available)
- Antiseptic

Reconstitution prior to use

SCULPTRA is reconstituted in the following way:

1. Remove the flip-off cap from the vial and clean the penetrable stopper of the vial with an antiseptic. If the vial, seal, or flip-off cap are damaged, do not use, and call sanofi-aventis Canada Inc. at 1-888-285-7872.
2. Attach 18 G sterile needle to a sterile single-use 5 mL syringe.
3. Draw 5 mL of SWFI, USP into the 5mL syringe.

4. Introduce 18 G sterile needle into the stopper of the vial and slowly add all SWFI, USP into the vial.
5. **Let the vial stand for at least 2 hours to ensure complete hydration; do not shake during this period.** SCULPTRA can be stored at room temperature up to 30°C during and after hydration. Refrigeration is not required.
6. After waiting at least 2 hours, agitate the vial until a uniform translucent suspension is obtained. A single vial swirling agitator may be used. Product should be agitated immediately prior to use. The reconstituted product is usable within 72 hours of reconstitution. Following reconstitution discard any product after 72 hours or after each patient use.
7. Clean the penetrable stopper of the vial with an antiseptic, and use a new 18 G sterile needle to withdraw an appropriate amount of the suspension (typically 1 mL) into a single-use 1-3 mL sterile syringe. Do not store the reconstituted product in the syringe.
8. Replace 18 G needle with a 26 G sterile needle before injecting the product into the deep dermis or subcutaneous layer. Do not inject SCULPTRA using needles of an internal diameter smaller than 26 G.
9. To withdraw remaining contents of the vial, repeat steps 6 through 8.

Patient Treatment

1. Patient Assessment

Before treatment with SCULPTRA, the patient should be informed completely of the indications, contraindications, warnings, precautions for use, possible side effects and mode of administration of SCULPTRA. A complete medical history should be taken to determine if the treatment is appropriate. Patients should be informed that more than one injection session is typically necessary to achieve the desired results.

2. Patient Preparation

As with all transcutaneous procedures, SCULPTRA injection carries a risk of infection. Standard precautions associated with injectable materials should be followed. As with all injectable products, universal precautions must be observed when there is a potential for contact with patient body fluids. The injection session must be conducted with aseptic technique.

3. The needle for injections

SCULPTRA should be injected using a 26 G sterile needle. Do not inject with needles smaller than 26 G and do not bend the needle. Agitate the product in the syringe as needed to maintain a uniform suspension throughout the procedure. Before injecting, expel some drops of the product from the prepared syringe with 26 G needle attached to eliminate air and to check for needle blockage. If the 26 G needle becomes occluded or dull during an injection session replacement may be necessary. Draw a small amount of air into the syringe between needle changes to assist in removing clogged particles.

4. The deep dermal plane

SCULPTRA should be injected into the deep dermis or subcutaneous layer. In order to control the injection depth of SCULPTRA, stretch/pull the skin opposite to the direction of the injection to create a firm injection surface. The 26 G sterile needle, bevel up, should be

introduced into the skin at an angle of approximately 30-40 degrees, until the desired skin depth is reached. A change in tissue resistance is evident when the needle traverses the dermal-subcutaneous junction. If the needle is inserted at too shallow an angle [i.e., into the mid or superficial (papillary) dermis] the bevel of the needle may be visible through the skin. If product is injected too superficially it will be evident as immediate or slightly delayed blanching in the injected area. If this occurs, the needle should be removed and the treatment area gently massaged.

5. Injecting: Threading or Tunneling

a) Technique

When the appropriate dermal plane is reached, the needle angle should be lowered to advance the needle in that dermal plane. Prior to depositing **SCULPTRA** in the skin, a reflux maneuver should be performed to assure that a blood vessel has not been entered. Using the threading or tunneling technique, a thin trail of **SCULPTRA** should then be deposited in the tissue plane as the needle is withdrawn. To avoid deposition in the superficial skin, deposition should be stopped before the needle bevel is visible in the skin.

b) Volume per injection

The volume of **SCULPTRA** should be limited to approximately 0.1 mL – 0.2 mL per each individual injection.

Volume per treatment area

The volume of product injected per treatment area will vary depending on the surface area to be treated. Multiple injections (typically administered in a grid or cross-hatched pattern) may be required to cover the targeted area. The total number of injections and thus total volume of **SCULPTRA** injected will vary based on the surface area to be corrected, not on the depth or severity of the deficiency to be corrected.

6. Injecting: Depot

a. Technique.

The depot technique is most appropriate for injections into areas of thin skin at the level of the upper zygoma or temples. When using this technique, **SCULPTRA** is injected as a small bolus. For the upper zygoma it is injected under the orbicularis oculi muscle. For the temples, it is injected in the temporal fascia.

b. Volume per injection.

The volume of **SCULPTRA** should be reduced to approximately 0.05 mL/injection. Following each injection, the area should be massaged.

7. Massage during the injection session

The treatment areas should be periodically massaged during the injection session to evenly distribute the product.

8. Degree of correction

The depressed area should never be overcorrected (overfilled) in an injection session. Limited correction of the treatment area allows for the gradual improvement of the depressed area over several weeks as the treatment effect occurs. Typically, patients will experience some

degree of edema associated with the injection procedure itself, which will give the appearance of a full correction by the end of the injection session (within about 30 minutes). The patient should be informed that the injection-related edema typically resolves in several hours to a few days, resulting in the ‘reappearance’ of the original contour deficiency.

9. Post-treatment care

Immediately following an injection session with SCULPTRA, redness, swelling, and/or bruising may be noted in the treatment area. Refer to **SIDE EFFECTS OF TREATMENT SECTION** for details. After the injection session, an ice pack (avoiding any direct contact of the ice with the skin) should be applied to the treatment area in order to reduce swelling. It is important to thoroughly massage the treatment area to evenly distribute the product. The patient should periodically massage the treatment area for several days after the injection session to promote a natural-looking correction.

10. Treat, Wait, Assess

During the first injection session with **SCULPTRA**, only a limited correction should be made. Do not overcorrect (overfill). The patient should be evaluated no sooner than two weeks after the injection session to determine if additional correction is needed. The original skin depression may initially reappear, but the depression should gradually improve within several weeks as the treatment effect of **SCULPTRA** occurs. The patient should be advised of the potential need for additional injection sessions at the first consultation.

SPECIAL STORAGE CONDITIONS

SCULPTRA powder should be stored at controlled room temperature (15-30°C) away from heat. Upon reconstitution, SCULPTRA can be stored up to 72 hours at room temperature. Refrigeration is not required. Do not freeze.

HOW SUPPLIED

SCULPTRA is supplied as a sterile freeze-dried preparation powder for injection in a clear glass vial, which is sealed by a penetrable stopper, covered by an aluminum seal with a flip-off cap. Each carton of **SCULPTRA** contains one vial.

IF THE VIAL, SEAL, THE FLIP-OFF CAP ARE DAMAGED, DO NOT USE, AND CONTACT sanofi-aventis Canada Inc. (SEE CONTACT INFORMATION PROVIDED ABOVE).

After use, treatment syringes and needles may be potential biohazards. Discard the needles and syringes in a safe disposal container.

This leaflet was last approved on October 14, 2009

Manufacturer

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