**Caution:** Federal (USA) law restricts this device to sale by or on the order of a licensed physician or properly licensed healthcare professional.

## A PATIENT'S GUIDE TO TREATMENT WITH SCULPTRA®

**SCULPTRA**
**(injectable poly-L-lactic acid)**

**Please review this information carefully before beginning your SCULPTRA Treatment.**

This guide is intended to help you become familiar with SCULPTRA use, as well as the expected correction, method of **injection**, post-**injection** skin care and possible **side effects**. You may request additional information such as the **product label** that further describes SCULPTRA and its clinical data from your healthcare professional. This information is also available on www.sculptrausa.com. This information is not meant to replace information provided by your healthcare professional. You should always ask your healthcare professional about your treatment and care.

## GLOSSARY

**Anesthetic:** A substance that causes loss of feeling or awareness. A topical or local anesthetic is a drug that causes temporary loss of feeling in a part of the body where it is placed.
**Antiseptic:** An agent that kills bacteria or prevents or slows growth of germs.
**Biocompatible:** A material that does not harm the body.
**Biodegradable:** A material that can be broken down by the body.
**Collagen:** The most common protein found in the body. Collagen is used to form a framework to support cell and tissue.
**Hypersensitivity:** undesirable, discomfort producing reaction; or an allergic reaction.
**Injection:** Product delivery at the location of a hollow needle tip beneath the surface of the skin.
**Immunocompetent**: Has a healthy immune system
**Keloid formation/Hypertrophic scarring:** An overgrowth of scar tissue at the site of a skin injury. Keloids/hypertrophic scars may occur around surgical cuts, traumatic wounds, vaccination sites, burns, or minor scratches. Hypertrophic scarring commonly resolves during the first year after injury; keloid formation most commonly does not resolve.
**Nasolabial fold/wrinkle:** Lines between the nose and the corner of the mouth.
**Nodule:** Lump under the surface of the skin that is greater than 5 mm, may be visible or not visible, but can be felt when pressed.
**Papule:** Lump under the surface of the skin that is less than 5 mm and not visible, but can be felt when pressed.
**Poly-L-lactic acid:** A man-made lactic acid polymer that is biocompatible and biodegradable.
**Product label:** Product information for healthcare professionals
**Side effect:** An unwanted event caused by use of the product.
**Wrinkle:** age-related defect in the contour of the skin surface.
**Wrinkle Assessment Scale (WAS):** A six point photo-numeric scale for the assessment of nasolabial fold wrinkles (see Figure 1).

**Wrinkle filler:** A product that is injected under the surface of skin to fill a space to decrease the appearance of a cosmetic facial contour deficiency such as facial lines, wrinkles or folds.

## WHAT IS SCULPTRA?

SCULPTRA is a sterile, injectable, **biocompatible**, **biodegradable** material that is made of very small particles of a synthetic polymer named "**poly-L-lactic acid**" (PLLA), carboxymethylcellulose (USP), non-pyrogenic mannitol (USP) and sterile water for **injection** (USP). While the time needed for SCULPTRA to resorb in humans is not known, in rabbits, particles were visible at over one year after **injection**.

## WHO MIGHT BENEFIT FROM TREATMENT WITH SCULPTRA?

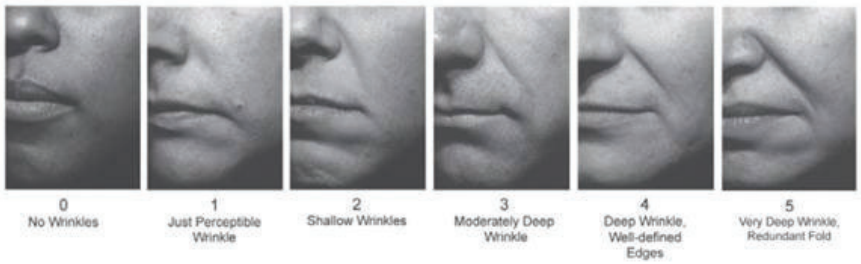
SCULPTRA is intended for use in people with healthy immune systems. SCULPTRA is injected in or under the facial skin through a small needle. SCULPTRA may be used for:

- correction of shallow to deep nasolabial fold contour deficiencies and other facial **wrinkles**.
- correction of fine lines and **wrinkles** in the cheek region.

A treatment regimen of SCULPTRA consists of up to 4 **injection** sessions scheduled 3-4 weeks apart.

SCULPTRA may provide cosmetic correction of nasolabial fold contour deficiencies and other facial **wrinkles** with a **Wrinkle Assessment Scale (WAS)** of 2, 3, or 4 as shown in the following photos: In the first US clinical study, optimal correction at 9 weeks after initial **injection** was most commonly found to be a 0.5 to 1-point decrease (improvement) in WAS.

FIGURE 1
WRINKLE ASSESSMENT SCALE (WAS)




SCULPTRA may provide cosmetic correction of fine lines and **wrinkles** in the cheek region in patients that have many superficial lines or a few shallow **wrinkles** to many shallow **wrinkles** of a few moderate depth **wrinkles** in the cheek region.

Your healthcare professional can help you determine if you might benefit from SCULPTRA and the optimal cosmetic correction expected for you.

## WHO SHOULD NOT GET SCULPTRA? (CONTRAINDICATIONS)

You should not get SCULPTRA if you:

- Have severe allergies with a history of severe reactions (anaphylaxis) or multiple severe allergies. Use of SCULPTRA may result in an allergic reaction.
- Are allergic to any ingredient of SCULPTRA: "**poly-L-lactic acid**" (PLLA), carboxymethylcellulose (USP) or non-pyrogenic mannitol (USP).
- Previously had or have risks factors for **hypertrophic scarring** or **keloid formation**.

## WHAT SHOULD I BE AWARE OF BEFORE RECEIVING SCULPTRA INJECTIONS (WARNINGS AND PRECAUTIONS)?

Warning: One of the risks with using this product is unintentional **injection** into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial **injections**, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin. If you have changes in your vision, signs of a stroke (including sudden difficulty speaking, 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 treatment, you should notify your healthcare professional immediately.

The use of SCULPTRA if you have skin sores, pimples, rashes, hives, cysts, or infections should be postponed until healing is complete. Use of SCULPTRA where these are present could delay healing or make your skin problems worse.

A reported **side effect** following treatment with SCULPTRA are lumps and bumps (**nodules**) that appear in the treated area. These could be visible or are not visible but can be felt under the skin. The risk of these lumps and bumps occurring could possibly be increased if you inject large volumes of the product at the same place, and in particular if you treat the deep **wrinkles** in the corner of your mouth (smile lines). These lumps or bumps usually go away on their own or after treatment with drugs, but surgery could in some cases be required.

The following are important treatment considerations for you to discuss with your doctor and understand in order to help avoid unsatisfactory results and complications.

- SCULPTRA has not been studied under the age of 18.
- Tell your healthcare professional if you are pregnant, planning to become pregnant, or breastfeeding. The safety of SCULPTRA has not been studied in women who are pregnant or breastfeeding.
- Tell your healthcare professional if you are taking any medications used to decrease the body's natural defense system (immunosuppressants). SCULPTRA **injections** may then result in an increased risk of infection.
- Tell your healthcare professional if you have a bleeding disorder or are taking any medication that can thin your blood or prolong bleeding, such as aspirin and warfarin. As

with any **injection** procedure this may increase your risk of bruising or bleeding at the **injection** site.

- Avoid or minimize hard (strenuous) exercise and exposure to extensive sun, UV lamps, indoor tanning beds/booths, or extreme temperatures within the first 24 hours after treatment with SCULPTRA. Any of these may cause temporary redness, swelling, pain and/or itching at the **injection** site.
- Tell your healthcare professional if you have recently had skin therapies such as laser treatment, mechanical or chemical peels or hair removal. This may lead to increased risk of **side effects** such as redness, swelling, heat or pain of the skin.

If you have any additional questions about any topic in this section, please discuss further with your healthcare professional.

In addition to the other information contained in this guide, you should be aware of the following: It is unknown whether SCULPTRA may be seen during radiologic imaging of your face and SCULPTRA may be visible via ultrasound and MRI. If you are having an ultrasound or MRI performed on the area injected with SCULPTRA, inform your healthcare professional that you have SCULPTRA injected in the area. In an animal study, SCULPTRA implants were observed in 100% of the animals via MRI and ultrasound imaging 24 hours after **injection**. Ninety (90) days after **injection**, SCULPTRA was observed in 30% of the animals via ultrasound and no animals via MRI. SCULPTRA was not observed at either time point via CT scan or standard, plain radiography.

## HOW DOES SCULPTRA WORK?

**Collagen** production in the body decreases as you get older and/or are exposed to the sun. **Wrinkles** are one of the first visible signs of this. SCULPTRA is injected into the deep layer of the skin where **collagen** naturally exists and is made. SCULPTRA works by initially filling a **wrinkle** with small PLLA beads. As the beads biodegrade the body may produce new **collagen** where SCULPTRA is injected. SCULPTRA is injected with multiple small **injections** using a fine needle to correct **nasolabial fold** contour deficiencies, other facial **wrinkles** or fine lines and **wrinkles** in the cheek region.

## WHAT WERE THE RESULTS OF THE U.S. CLINICAL STUDIES CONDUCTED ON SCULPTRA?

A U.S. study was conducted to compare the safety and effectiveness of SCULPTRA and a control for the treatment of facial **wrinkles**. The treatment consisted of one to four visits at three (3) week intervals during which the 233 subjects received treatment with either SCULPTRA (n=116) or the control (n=117). Subjects were followed for 13 months after the last treatment. Doctors graded standardized photographs to evaluate the **wrinkle** reduction effectiveness of both SCULPTRA and the control. Safety was evaluated by comparing the number and severity of **side effects** during the study. **Side effects** are summarized in the table below.

**TABLE 1: NUMBER OF SUBJECTS WITH INJECTION-RELATED SIDE EFFECTS OBSERVED IN SCULPTRA AESTHETIC U.S. CLINICAL STUDY**

| SIDE EFFECTS TYPE<br>*Immediate, as recorded in subject diaries* | 116 Subjects<br>N (%) |
|---|---|
| Localized Swelling | 94 (81.0%) |
| Localized Tenderness | 94 (81.0%) |
| Localized Redness | 90 (77.6%) |
| Post-Injection Site Pain | 82 (70.7%) |
| Localized Bruising | 75 (64.7%) |
| Bleeding from Site(s) | 39 (33.6%) |
| Localized Itching | 23 (19.8%) |
| Other | 19 (16.4%) |
| *DELAYED, as reported by physicians* | |
| Nodules and papules | 20 (17.2%) |
| Delayed injection site pain* | 1 (0.9%) |
| Average time to appearance after first injection: | |
| Nodules | 209 days |
| Papules | 159 days |
| Average time of duration: | |
| Nodules | 180 days |
| Papules | 176 days |

*One subject reported mild injection site pain approximately 20 months after first injection, no information on outcome was available at the end of the 25 month extension phase study

Most **side effects** were mild and resolved on their own; one small **papule** required treatment by the healthcare professional. Five new SCULPTRA-related events were reported more than 13 months after first **injection** with SCULPTRA in three subjects: 2 **papules** (1.9%), 1 **nodule** (0.9%) and 2 **injection** site pain (0.9%).

Results showed that SCULPTRA had effects lasting up to 25 months in some patients for the treatment of **nasolabial fold wrinkles** as compared to control. Both treatments were well tolerated.

SCULPTRA was tested in an additional study with 80 patients to ensure it was safe and effective to use in treatment of **nasolabial folds** but diluted in a larger volume and with the **anesthetic** lidocaine added to the solution. The patients included were 76 women and 4 men and were from various ethnic groups with skin tones ranging from pale to dark skin. 59 of these patients received SCULPTRA in the larger dilution volume with the local **anesthetic** lidocaine added. Each patient included had expressed a desire to improve the appearance of their **nasolabial folds**.
The study was conducted by 5 different doctors in 5 different locations across the United States. Patients who participated received up to four treatments with SCULPTRA at four-week intervals. Each patient was monitored for 48 weeks following the initial treatment to measure the effects of the treatments. For each patient, the amount of product used was based on their individual needs. Each patient was evaluated by a doctor other than one who had performed the treatment, in order to objectively measure improvements in appearance over 48 weeks. Patients also evaluated themselves.

To measure **side effects** following the procedure, doctors reported unwanted signs and symptoms and each patient kept a diary for 28 days to record **side effects**. These were then shared with the doctors.

Many patients reported the following **side effects** at the site where they received the **injection** in their diary:

- Swelling
- Redness
- Pain/Tenderness
- Bruising

Most patients said these temporary **side effects** to the **injection** procedure were mild to moderate and disappeared within 1-2 weeks.

Other side-effects reported in the studies included bleeding, numbness, tingling sensation, **injection** site hardening, pain and itching at the **injection** site as well as dry skin, lumps/bumps formation, herpes, headache and runny or congested nose.

Results showed that SCULPTRA had effects for most patients for the treatment of nasolabial fold **wrinkles** up to Week 48 after the initial treatment in both treatment groups. The treatment was well tolerated.

Patients who received SCULPTRA diluted in a larger volume and with the **anesthetic** lidocaine added to the solution were monitored for an additional 48 weeks in an extension study. No additional treatment was given. Each patient was evaluated by a doctor and patients also evaluated themselves in order to measure improvements in appearance up to 96 weeks after the initial treatment. No **side effects** were reported in the extension study. Results showed that SCULPTRA had effects for most patients for the treatment of nasolabial fold **wrinkles** up to Week 96.

SCULPTRA was also tested in 149 patients in a study to ensure it was safe and effective to use in treatment of fine lines and **wrinkles** in the cheek region, diluted in the larger volume and with the **anesthetic** lidocaine added to the solution. The patients included were from various ethnic groups with skin tones ranging from pale to dark skin. Each patient included had expressed a desire to improve the appearance of their cheek **wrinkles**.

The study was conducted by 13 different doctors in 13 different locations across the United States. Patients who participated received up to four treatments with SCULPTRA at four- to nine-week intervals. Each patient was monitored for 24 months following the initial treatment to measure the effects of the treatments. One hundred four (104) patients completed the study. For each patient, the amount of product used was based on their individual needs.

Each patient was evaluated by a doctor other than one who had performed the treatment, in order to objectively measure improvements in appearance over 24 months. Patients also evaluated themselves. To measure **side effects** following the procedure, doctors reported unwanted signs and symptoms and each patient kept a diary for 28 days to record **side effects**. These were then shared with the doctors.

Many patients reported the following **side effects** at the site where they received the **injection** in their diary:

- Swelling
- Redness
- Pain/Tenderness
- Bruising
- Itching
- Lumps/Bumps

Most patients said these temporary **side effects** to the **injection** procedure were mild to moderate and disappeared within 1-2 weeks.

Other side-effects reported in the study included dizziness, headache, abnormal sensation in the eye, as well as **injection** site irritation, discoloration and skin mass.

Three patients had changes in vision at visits after the treatment. These occurrences were due to the patients not wearing their glasses or contact lenses.

Results showed that SCULPTRA had effects for most patients for the treatment of fine lines and **wrinkles** in the cheek region up to Month 24 after the initial treatment. The treatment was well tolerated.

## WHAT ADVERSE EVENTS HAVE BEEN REPORTED THROUGH VOLUNTARY POST-MARKETING SURVEILLANCE OF SCULPTRA USE IN AND OUTSIDE OF THE US?

The most commonly reported serious adverse events with a frequency greater than 5 reported events were lumps or **nodules** at the **injection** site, delayed swollen lumps (granulomas), redness, pain/tenderness, inflammation, swelling, **hypersensitivity**, itching, mass/induration (hardening), bruising, discoloration, device ineffective, symptoms of reactivation of herpes infection, ischemia/necrosis (restricted blood flow leading to the death of skin), neurological symptoms (such as a reduced sense of touch), blisters/vesicles, device dislocation, infection/abscess, visual disturbance including transient blurred vision, reduced visual acuity, watery eyes, drooping of upper eyelid, dry eye, blindness, skin discoloration, **injection** site reactions including burning sensation, warmth and irritation, scarring, facial asymmetry, bleeding, acne, and non-dermatological events including headache, joint pain, anxiety, nausea, insomnia, difficulty breathing, dizziness, swollen lymph nodes, and depression.

- **Injection** site **nodules** mostly occurred several months after **injection**, starting from 1-2 months to 14 months after last SCULPTRA administration. In some cases, the **nodules** went away on their own or after treatment with corticosteroid **injections**; other **nodules** lasted up to 2 years. In some cases, surgery was required to remove the **nodules**.
- Serious delayed swollen lumps (granulomas) were reported from several months after **injection** to more than 1 year after **injection**. These were treated with corticosteroid **injections** or surgical procedures. Some cases involving the area under the eyes (infraorbital) or **injection** in the red area of lips (lip vermilion) required hospitalization. For cases where information was available, the patients were recovering following treatment.
- Serious redness, pain, itching, bruising and heat sensation, were reported within 24 hours after **injection**. Treatment included corticosteroids, anti-histamines and/or anti-inflammatories. These went away within 7-10 days.
- Serious swelling was reported following **injection**. Treatment included corticosteroids, anti-histamines and/or anti-inflammatories. Swelling went away within 7-10 days.
- Serious **hypersensitivity** reactions have been reported, including severe facial swelling (Quincke's edema), with symptoms appearing from 1 day to 1 week after **injection**. Patients recovered without complication after treatment with intravenous corticosteroids and antihistamines.
- Serious infections at the **injection** site have been reported, starting from 1 day to one week after **injection**. Of these cases a few required hospitalization for intravenous antibiotics. All patients recovered or were recovering at the last contact.

Other events that were reported included: application site discharge, fatigue, hypertrophy of skin, **injection** site atrophy, **injection** site hardness (induration), lack of effectiveness, malaise, photosensitive reaction, scar, skin discoloration, skin rash, skin roughness, skin wrinkling, skin tightness, skin dryness, skin disease inflammation (skin sarcoidosis), skin whitening at the **injection** site, dilated small blood vessels (telangiectasias), hives (urticaria), visible lumps with or without inflammation or discoloration.

Warning: One of the risks with using this product is unintentional **injection** into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial **injections**, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin. If you have changes in your vision, signs of a stroke (including sudden difficulty speaking, 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 treatment, you should notify your healthcare professional immediately.

## ARE SKIN TESTS NEEDED BEFORE TREATMENT WITH SCULPTRA?

No skin testing is required prior to use in **immunocompetent** people with skin that heals normally.

## ARE THE RESULTS FROM SCULPTRA IMMEDIATE?

No. Unlike other **wrinkle** fillers, SCULPTRA provides a gradual improvement of the depressed area over several weeks as the treatment effects occur. During the initial treatment session with SCULPTRA, the contour deficiency, line or **wrinkle** should be under-corrected, not fully-corrected or over-corrected. It may seem that your treatment worked immediately because of swelling caused by **injection** and the water used to dilute SCULPTRA. This usually resolves in several hours to a few days and may cause the original defect to reappear: you may look as you did before your treatment. Visible contour, line or **wrinkle** correction results appear slowly. Your healthcare professional should see you again in three or more weeks to decide if you need additional **injections**.

## HOW OFTEN ARE SCULPTRA TREATMENTS GIVEN AND HOW MANY TREATMENTS ARE REQUIRED?

Your healthcare professional should see you at approximately three-four weeks after each treatment session to assess whether you need additional treatment. You may need one to four treatment sessions (typically three) to achieve the optimal correction possible. The safety and effectiveness of SCULPTRA has only been studied in a single treatment regimen of up to four sessions at three four-week intervals.

## HOW LONG DO SCULPTRA TREATMENT EFFECTS LAST?

In a U.S. clinical study, treatment results for some subjects lasted for up to 25 months after the last treatment session. However, the improvement depended on the severity of the contour deficiency that a subject had before treatment. Discuss with your health care provider the optimal cosmetic correction you may expect.

## DO INJECTIONS OF SCULPTRA HURT?

As with any **injection**, to decrease pain during **injection**, a topical or a local **anesthetic** may be used when injecting SCULPTRA. In a U.S. clinical study, subjects recorded pain in diaries: 71% of all treated patients reported some pain after first **injection**, 14% of subjects had moderate pain. Most pain resolved in less than 24 hours.

## WHAT CAN I EXPECT TO HAPPEN AT A TREATMENT SESSION?

Your healthcare professional will answer all of your questions and ask about your medical history to determine if SCULPTRA **injection** is appropriate for you. Tell your healthcare professional about all the medicines you are taking, even over the counter medicines or treatments. You and your healthcare professional will determine if a topical or local **anesthetic** is needed.

- To prepare for an **injection** session, all make-up should be removed.
- An **injection** grid will be decided for each facial **wrinkle** that is candidate for this treatment and the area to be injected will be cleaned with an **antiseptic**.
- SCULPTRA will be injected in multiple small amounts into or under the skin using a fine needle.
- After **injection**, the treated area should be massaged to distribute the product evenly.
- An ice pack wrapped in cloth should be applied to the treatment area to help reduce swelling unless otherwise directed by your healthcare professional. Avoid any direct contact of the ice with the skin.

## WHAT CAN I EXPECT AFTER TREATMENT?

As with any injectable **wrinkle** filler, you can expect **injection**-related **side effects**, such as bleeding, tenderness or pain/discomfort, redness, bruising, or swelling. These **side effects** generally resolve within a few hours to a few days but could last for 14 days or longer. For more information on adverse events, see previous sections ”RESULTS OF THE U.S. CLINICAL STUDIES” and ”WHAT ADVERSE EVENTS HAVE BEEN REPORTED THROUGH VOLUNTARY POST-MARKETING SURVEILLANCE OF SCULPTRA AND SCULPTRA USE IN AND OUTSIDE OF THE US?

Your health care provider will give you specific post-treatment care instructions. Some specific instructions you should follow after treatment are:

- Massage the treated area for 5 minutes 5 times per day for 5 days after your treatment.
- Within the first 24 hours after your treatment, apply ice or an ice pack wrapped in cloth (avoid putting ice directly on your skin) to the treatment area to help reduce swelling
- Avoid or minimize hard (strenuous) exercise and exposure to extensive sun, UV lamps, indoor tanning beds/booths, or extreme temperatures within the first 24 hours after treatment with SCULPTRA.
- Report any worsening or longer-lasting signs of symptoms to your healthcare professional. Seek immediate medical attention if you develop symptoms such as unusual pain, vision changes, a white appearance of skin near the **injection** site, or any signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion) during or shortly after the procedure (http://www.nlm.nih.gov/medlineplus/stroke.html).

**HOW QUICKLY CAN I GET BACK TO MY DAILY ACTIVITIES?**

Most patients are able to get back to their activities immediately following treatment.

**WHEN WILL I BE ABLE TO APPLY MAKE-UP AFTER TREATMENT?**

Make-up may be applied a few hours after treatment if there are no complications such as open wounds or bleeding.

**WHAT ARE MY OTHER OPTIONS FOR TREATMENT?**

There are a variety of dermal fillers available in the US. Prices, safety and effectiveness vary. Consult with your healthcare professional to determine which one is right for you.

**FOR FURTHER QUESTIONS AND INFORMATION, OR TO REPORT ANY SIDE EFFECTS, PLEASE CALL GALDERMA LABORATORIES, L.P. AT 1-855-425-8722**

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