89031167
Rev. 07/16

sculptra® aesthetic
injectable poly-L-lactic acid

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SCULPTRA® Aesthetic
(injectable poly-L-lactic acid)

The SCULPTRA Aesthetic implant package (i.e., lyophilized vials) is provided sterile.

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

Information for the use of SCULPTRA® Aesthetic is provided in this Labeling for Physicians and the Instructions for Use, as well as in Labeling for Patients. BEFORE USING SCULPTRA® Aesthetic PLEASE READ THE FOLLOWING INFORMATION THOROUGHLY. Please direct any questions to Galderma Laboratories, L.P. Fort Worth, TX 76177 USA 1-855-425-8722

DEVICE DESCRIPTION

SCULPTRA® Aesthetic is an injectable implant containing microparticles of poly-L-lactic acid (PLLA), carboxymethylcellulose (USP), non-pyrogenic mannitol (USP) and sterile water for injection (USP). SCULPTRA Aesthetic is available in 367.5 mg dose vials and is to be reconstituted prior to use by the addition of 5 mL of Sterile Water for Injection, USP (SWFI) to form a sterile non-pyrogenic suspension.

INTENDED USE / INDICATIONS

SCULPTRA Aesthetic is indicated for use in immune-competent people as a single regimen for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate. (This corresponds to Wrinkle Assessment Scores (WAS) of 2 to 4 in Figure 2 and the cross-hatch injection technique presented in Figures 3-7 in the Instructions for Use Section).

CONTRAINDICATIONS

SCULPTRA Aesthetic should not be used in any person who has hypersensitivity to any of the components of SCULPTRA Aesthetic (see DEVICE DESCRIPTION).

SCULPTRA Aesthetic should not be used in patients with known history of or susceptibility to keloid formation or hypertrophic scarring.

WARNINGS

- SCULPTRA Aesthetic has unique injection requirements, which include injection with tunneling technique in a grid pattern that is medial to the nasolabial fold contour defect that is to be corrected (see Figures 3-7 in the INSTRUCTIONS FOR USE). The safety of other methods of injection has not been evaluated in clinical studies.
- Do not overcorrect (overfill) the contour deficiency of the nasolabial fold contour defect because the depression is expected to gradually improve during several weeks after injection as the treatment effect of SCULPTRA Aesthetic occurs (see INSTRUCTION FOR USE - Patient Treatment).
- SCULPTRA Aesthetic must not be implanted into blood vessels.
- Introduction of product into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft tissue fillers, for example inject the product slowly and apply the least amount of pressure necessary. Rare but serious adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate health care practitioner specialist should an intravascular injection occur.
- SCULPTRA Aesthetic use at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes or hives) or infection is present should be deferred until the inflammatory process has resolved and is controlled.
- Injection site reactions to SCULPTRA Aesthetic have included delayed occurrence of subcutaneous papules and nodules, hematoma, bruising-ecchymosis, bleeding, edema, discomfort, inflammation, and erythema. The subcutaneous papules and nodules were often confined to the injection site, typically palpable, asymptomatic and non-visible, occurring days to months after injection and had a prolonged time course to resolution. See ADVERSE EVENTS section for details.
- The kinetics of SCULPTRA Aesthetic resorption in humans has not been determined. In an intradermal implantation study in rabbits all animals had "several relatively large remnants" of injectable PLLA visible at 64 weeks after implantation. The tissue response to injectable PLLA was generally greater than the vehicle or negative plastic controls and was described as a chronic, granulomatous reaction characterized by foreign body giant cells and macrophages. The tissue reaction was confined to the area between particles, did not involve the surrounding tissue and was not unexpected, because it was consistent with the persistent and particle nature of injectable PLLA.

PRECAUTIONS

- SCULPTRA Aesthetic should only be used by a healthcare practitioner trained to correct shallow to deep nasolabial fold contour deficiencies and other facial wrinkles, in which deep dermal grid pattern (cross-hatch) injection technique is appropriate after the health care practitioner is fully familiar with the product, WAS, product educational materials, and the entire package insert and patient labeling.
- In order to minimize the risks of potential complications, this product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
- Health care practitioners are encouraged to discuss all potential risks of soft tissue injection with their patients prior to treatment and ensure that patients are aware of signs and symptoms of potential complications.
- The safety and effectiveness of injecting Sculptra Aesthetic: 1) in larger amounts, 2) at different frequencies, 3) at anatomic sites different than the deep dermis of the nasolabial folds, 4) with different techniques, or 5) at anatomic sites that have had previous dermal filler injections, (including previous SCULPTRA Aesthetic injection), have not been evaluated.
- Long term safety and effectiveness of SCULPTRA Aesthetic beyond 25 months after last injection have not been investigated in clinical trials.
- The safety and effectiveness of SCULPTRA Aesthetic for use in the lips has not been evaluated. Do not inject into the red area (vermillion) of the lip.
- SCULPTRA Aesthetic should be injected into the deep dermis. Superficial injections may be associated with increased local adverse events such as nodules and papules. Take special care when using SCULPTRA Aesthetic in patients with thin skin. Please refer to PATIENT TREATMENT for injection technique instruction.
- SCULPTRA Aesthetic injection in the peri-orbital area has not been studied. An increased risk of papules and nodules has been reported in published literature after injections in the periorbital area.
- Safety and effectiveness of SCULPTRA Aesthetic has not been evaluated in subjects who are pregnant, lactating, breast feeding, or under 18 years of age.
- Safety and effectiveness of SCULPTRA Aesthetic has not been evaluated in subjects with the following: history of keloid formation, hypertrophic scarring, connective tissue disease, active inflammatory conditions, bleeding disorders, active hepatitis, serious abnormalities in laboratory findings, disease such as cancer, stroke and/or myocardial infarction, on any immunosuppressive therapy, and/or with any other prior or concomitant treatment at the SCULPTRA Aesthetic treatment site.
- Safety and effectiveness of SCULPTRA Aesthetic has not been systematically evaluated with local anesthetics, other drugs or devices used during the same treatment session. The safety and effectiveness of the volume ratio of SCULPTRA Aesthetic mixed with local anesthetic or any drug or device has also not been assessed.
- Other filler products should not be directly mixed with SCULPTRA Aesthetic. No studies of interactions of SCULPTRA Aesthetic with drugs or other substances or implants have been made.
- The volume of SCULPTRA Aesthetic injection per surface area of a tunneling or threading injection grid has not been assessed for any WAS.
- It is not known whether SCULPTRA Aesthetic is radiopaque in humans. The microparticles of SCULPTRA Aesthetic may be visible on computer tomography (CT) scans, magnetic resonance imaging (MRI), ultrasound or standard, plain radiography. Patients should be informed that the device may be radiopaque, so that they can inform their health care professionals, including radiologists. In an animal study, SCULPTRA Aesthetic implants were observed in 10/10 rats via MRI and ultrasound imaging 24 hours after subcutaneous injection. Ninety (90) days after injection, SCULPTRA Aesthetic was observed in 3/10 rats via ultrasound and no animals via MRI. SCULPTRA Aesthetic was not observed at either time point via CT scan or standard, plain radiography.
- Safety and effectiveness data from clinical trials of SCULPTRA Aesthetic in non-Caucasians are limited.
- As with all transcutaneous procedures, SCULPTRA Aesthetic injection carries a risk of infection. Standard precautions to minimize infections associated with intradermal injectable materials should be followed.
- As with all injections, patients with coagulation defects or on concurrent anti-coagulant therapy are at increased risk for hematoma formation, bruising and/or bleeding at the injection site.
- As with all invasive procedures, SCULPTRA Aesthetic sessions should be conducted with aseptic technique. Observe universal precautions to minimize risks of potential contact with patient body fluids such as blood at the injection site.
- After use, treatment syringes and needles are considered contaminated biohazards. Handle and dispose contaminated syringes and needles in accordance with accepted medical practice and applicable local, state and federal requirements.
- The patient should be informed that he or she should minimize exposure of the treatment area to sun and avoid UV lamp exposure until any initial swelling and redness has resolved.
- If laser treatment, chemical peeling or any other procedure based on active dermal response is considered after treatment with SCULPTRA Aesthetic, there is a possible risk of eliciting an inflammatory reaction at the implant site. This also applies if SCULPTRA Aesthetic is administered before the skin has healed completely after such a procedure.
- SCULPTRA Aesthetic vials are for single patient use only. Do not reuse or resterilize the vial. Do not use if the package or vial is opened or damaged.

ADVERSE EVENTS

Clinical Trial

Controlled phase study (0-13 months)

A prospective, randomized clinical study was conducted at 10 centers in the US. Two hundred and thirty three (233), immune-competent and non-pregnant and non-breast feeding subjects with previously untreated nasolabial fold wrinkles and WAS of 2 through 4 received bilateral injections of either SCULPTRA Aesthetic or Cosmoplast in both nasolabial fold wrinkles during a maximum of 4 sessions over 9 weeks. Study treatment was planned to be stopped when the right and left nasolabial fold wrinkle reached WAS of 1 or 0, or the maximum of 4 treatment sessions were completed. Adverse events reported in subject diaries after initial treatment are summarized in Tables 1 (intensity) and 2 (duration) below. Adverse events described in the physician case reports are summarized in Table 3 below.

TABLE 1
INTENSITY OF ADVERSE EVENTS AFTER THE INITIAL TREATMENT SESSION, RECORDED IN THE 14 DAY SUBJECT DIARY
(Controlled Phase, 0-13 months)
All-Treated Population: Per Subject

Injection Procedure Related Event	SCULPTRA Aesthetic (First Treatment Session: N = 116)					Cosmoplast (First Treatment Session: N = 117)				
	Total subjects reporting symptoms[a] n (%)	Severity of Adverse Event[a]				Total subjects reporting symptoms[a] n (%)	Severity of Adverse Event[a]			
		Mild n	Moderate n	Severe n	Missing n		Mild n	Moderate n	Severe n	Missing n
Localized Swelling	94 (81.0)	64	24	5	1	76 (65.0)	60	13	1	2
Localized Tenderness	94 (81.0)	63	24	2	5	83 (70.9)	62	16	1	4
Localized Redness	90 (77.6)	63	23	1	3	88 (75.2)	63	23	1	1
Post-Injection Site Pain	82 (70.7)	58	16	1	7	65 (55.6)	50	7	1	7
Localized Bruising	75 (64.7)	44	22	6	3	50 (42.7)	26	18	1	5
Bleeding from Site(s)	39 (33.6)	29	3	0	7	43 (36.8)	33	5	0	5
Localized Itching	23 (19.8)	14	1	0	8	34 (29.1)	24	6	1	3
Nodules / papules / lumps	4 (3.4)	2	1	0	1	14 (12.0)	4	7	1	2
Other[b]	19 (16.4)	7	8	1	3	22 (18.8)	11	6	3	2
Total	113 (97.4)	48	54	11	0	110 (94.0)	61	42	5	2

[a] Subjects experiencing multiple episodes of a given adverse event are counted once for that event within the most severe category.
[b] Subjects who reported multiple events in the "Other" category are counted only once within the most severe category. Adverse Events reported as "Others" are headache, dry skin, skin peeling, rash at injection, pimples, improvement of allergy symptoms, needle marks, sinus pressure, bruising, mouth sores, tenderness and twitching of nostril.

TABLE 2
DURATION OF ADVERSE EVENTS AFTER THE INITIAL TREATMENT SESSION, RECORDED IN THE 14 DAY SUBJECT DIARY
(Controlled Phase, 0-13 months)
All-Treated Population: Per Subject

Injection Procedure Related Event	SCULPTRA Aesthetic (First Treatment Session: N = 116)							Cosmoplast (First Treatment Session: N = 117)						
	Total subjects reporting symptoms[a] n (%)	Duration of Adverse Event[a]						Total subjects reporting symptoms[a] n (%)	Duration of Adverse Event[a]					
		<1 hour	1-24 hrs	2-7 days	8-14 days	≥15 days	Missing		<1 hour	1-24 hrs	2-7 days	8-14 days	≥15 days	Missing
Localized Swelling	94 (81.0)	4	48	35	2	0	5	76 (65.0)	6	34	29	2	2	3
Localized Tenderness	94 (81.0)	7	45	32	1	4	5	83 (70.9)	6	33	29	2	10	3
Localized Redness	90 (77.6)	13	50	24	0	0	3	88 (75.2)	11	25	33	3	13	3
Post-Injection Site Pain	82 (70.7)	21	44	14	0	1	2	65 (55.6)	16	35	8	0	4	2
Localized Bruising	75 (64.7)	6	11	44	7	2	5	50 (42.7)	3	12	25	9	0	1
Bleeding from Site(s)	39 (33.6)	28	6	1	0	0	4	43 (36.8)	35	6	0	0	0	2
Localized Itching	23 (19.8)	9	5	6	0	0	3	34 (29.1)	5	8	13	2	4	2
Nodules / papules / lumps	4 (3.4)	0	0	2	0	1	1	14 (12.0)	0	0	3	0	9	2
Other[b]	19 (16.4)	0	3	10	2	3	1	22 (18.8)	1	2	7	2	8	2
Total	113 (97.4)	2	24	67	10	9	1	110 (94.0)	5	18	54	5	27	1

[a] Subjects experiencing multiple episodes of a given adverse event are counted once for that event within the longest duration category.
[b] Subjects who reported multiple events in "Other" category are counted only once within the longest duration category. For list of adverse events categorized as "other", see table 1.

TABLE 3
PHYSICIAN REPORTED* ADVERSE EVENTS
AFTER ALL TREATMENTS REGARDLESS OF RELATIONSHIP TO THE DEVICE OCCURRING IN >1% OF SUBJECTS
(Controlled Phase, 0-13 months)
All-Treated Population: Per Subject

ADVERSE EVENTS (MedDRA Preferred Term)	SCULPTRA Aesthetic N = 116 N (%)	Cosmoplast N = 117 N (%)
injection site pain	11 (9.5)	12 (10.3)
application site nodule**	10 (8.6)	11 (9.4)
application site papule***	10 (8.6)	4 (3.4)
nasopharyngitis	7 (6.0)	9 (7.7)
headache	5 (4.3)	4 (3.4)
injection site erythema	4 (3.4)	38 (32.5)
acne	3 (2.6)	4 (3.4)
pain	3 (2.6)	2 (1.7)

TABLE 3 (continued)
PHYSICIAN REPORTED* ADVERSE EVENTS
AFTER ALL TREATMENTS REGARDLESS OF RELATIONSHIP TO THE DEVICE OCCURRING IN >1% OF SUBJECTS
(Controlled Phase, 0-13 months)
All-Treated Population: Per Subject

ADVERSE EVENTS (MedDRA Preferred Term)	SCULPTRA Aesthetic N = 116 N (%)	Cosmoplast N = 117 N (%)
injection site dermatitis	3 (2.6)	1 (0.9)
hypertension	3 (2.6)	0 (0.0)
injection site haemorrhage	2 (1.7)	6 (5.1)
swelling	2 (1.7)	2 (1.7)
fracture	2 (1.7)	2 (1.7)
urinary tract infection	2 (1.7)	2 (1.7)
streptococcal infection	2 (1.7)	0 (0.0)
tooth abscess	2 (1.7)	0 (0.0)
syncope vasovagal	2 (1.7)	0 (0.0)
cough	2 (1.7)	0 (0.0)
injection site pruritus	1 (0.9)	12 (10.3)
sinusitis	1 (0.9)	6 (5.1)
application site dryness	1 (0.9)	5 (4.3)
influenza	1 (0.9)	5 (4.3)
injection site swelling	1 (0.9)	4 (3.4)
bronchitis	1 (0.9)	2 (1.7)
upper respiratory tract infection	1 (0.9)	2 (1.7)
injection site discoloration	0 (0.0)	2 (1.7)
injection site eczema	0 (0.0)	2 (1.7)
skin tightness	0 (0.0)	2 (1.7)

* Includes all subjects with nodules and papules regardless of duration
** Application site nodule is a lesion equal to or greater than to 5 mm, typically palpable, asymptomatic and non-visible
***Application site papule is a lesion less than 5 mm, typically palpable, asymptomatic and non-visible

Adverse events that occurred with SCULPTRA Aesthetic at an incidence of <1%:
Acrochordon, anxiety, colitis, contusion, corneal abrasion, cyst, depression, dermatitis, eczema, gastritis, herpes simplex, hypercholesterolemia, hypersensitivity, hypothyroidism, injection site desquamation, injection site rash, lower respiratory infection, lymphadenopathy, migraine, muscle injury, muscle twitching, myalgia, osteoarthritis, osteopenia, pruritus, rheumatoid arthritis, gastroenteritis, skin burning sensation, spider vein, staphylococcal infection, stress symptoms, tooth infection, toothache, vaginal infection.

Extension Phase Study (13 to 25 months)

A total of 106 subjects treated with SCULPTRA Aesthetic in the initial 13 month study were followed for an additional 12 months (25 months total) after their last treatment. Only SCULPTRA Aesthetic-related adverse events were collected on the physician case report forms. Five new device-related adverse events were reported in three subjects: 2 subcutaneous papules (1.9%), 1 nodule (0.9%) and 2 injection site pain (0.9%).

Nodules and Papules

In the controlled clinical study the percentage of subjects with nodules and/or papules was greater after SCULPTRA Aesthetic [(17.2% (20/116)] than after the control treatment [(12.8%) (15/117)]. This reflects 8 Sculptra Aesthetic subjects who experienced nodules, 10 Sculptra Aesthetic patients who experienced papules and 2 Sculptra Aesthetic subjects who experienced both nodules and papules.

After the first SCULPTRA Aesthetic injection session, time to onset for nodules was 160 days (median) and 209 days (mean) and for papules 55 days (median) and 159 days (mean). After SCULPTRA Aesthetic injection, the duration of nodules was 100 days (median) and 180 (mean) days, for papules was 110 days (median) and 176 days (mean).

One subject with a papule required a single intralesional corticosteroid injection and the event resolved. For 3 subjects with nodules/papules, no information on outcome was available at the end of the 25 month extension phase study. For all remaining subjects, nodules/papules resolved spontaneously. None of these events were reported as a serious adverse event by the investigator.

Table 4 contains, for the SCULPTRA Aesthetic (0-25 months) and Cosmoplast (0-13 months) groups, summaries of the number of nodules and papules per baseline skin type, age group, and race stratified by baseline WAS. Summaries of the time to onset and duration of nodules and papules, stratified by baseline WAS are also presented.

TABLE 4
SUMMARY OF NODULES AND PAPULES, SCULPTRA AESTHETIC (SA) and COSMOPLAST (COS)

Baseline (Pre-Injection, before first treatment) WAS	1		2		3		4		ALL	
Treatment	SA	COS	SA	COS	SA	COS	SA	COS	SA	COS
Number of pt injected (N)	6	4	55	41	41	55	14	17	116	117
Patients with nodule	0 0%	0 0%	4 7.3%	4 9.8%	4 9.8%	6 10.9%	2 14.3%	1 5.9%	10 8.6%	11 9.4%
Patients with papule	0 0%	0 0%	7 12.7%	1 2.4%	5 12.2%	1 1.8%	0 0%	2 11.8%	12 10.3%	4 3.4%
Demographics										
Patients Nodules or Papules per Fitzpatrick Skin Type										
Fitzpatrick Skin Type = 1	0	0	1	0	1	0	0	1	2	1
Fitzpatrick Skin Type = 2	0	0	4	2	3	2	0	1	7	5
Fitzpatrick Skin Type = 3	0	0	4	2	2	4	2	1	8	7
Fitzpatrick Skin Type = 4	0	0	2	1	1	1	0	0	3	2
Fitzpatrick Skin Type = 5	0	0	0	0	0	0	0	0	0	0
Fitzpatrick Skin Type = 6	0	0	0	0	0	0	0	0	0	0
Patients Nodules or Papules per age group										
Patients <35 y.o.	0	0	0	0	0	0	0	0	0	0
Patients 35-55 y.o.	0	0	7	5	4	4	1	1	12	10
Patients >55 y.o.	0	0	4	0	3	3	1	2	8	5
Patients Nodules or Papules per race										
Caucasian	0	0	10	4	5	6	2	3	17	13
Hispanic	0	0	0	1	2	1	0	0	2	2
Black / Asian /Other	0	0	1	0	0	0	0	0	1	0
Time (days) from first device injection to start of event [median, mean, min, max]										
Nodules - median days to event onset	0	0	261	4.5	66	2	48.5	1	160	1
Nodules - mean days to event onset	0	0	255.4	5.0	221.1	11	48.5	1	208.7	7.9
Nodules – time to onset minimum days maximum days	0	0	1 447	1 10	1 669	1 43	1 96	1 1	1 669	1 43
Papule - median days to event onset	0	0	49	1	64	25	0	22	54.5	22
Papules - mean days to event onset	0	0	130.7	1	197.8	25	0	17.7	158.7	15.8
Papules – time to onset minimum days maximum days	0	0	4 500	1 1	1 586	25 25	0	1 30	1 586	1 30
Event Duration, days [median, mean, min, max]										
Nodule - median duration days	0	0	357	158.5	50	26	56.5	97	99.5	41
Nodule - mean duration days	0	0	315.4	196.8	118.9	31	56.5	97	180.1	97.3
Nodule duration minimum days maximum days	0	0	22 543	8 462	4 489	3 68	18 95	97 97	4 543	3 462
Papule - median duration days	0	0	157	45	62	6	0	16	109.5	16
Papule - mean duration days	0	0	186.1	45	161.6	6	0	17.7	175.9	20.8
Papules – duration minimum days maximum days	0	0	9 407	45 45	8 512	6 6	0	15 22	8 512	6 45

No significant associations were found between incidence of nodule/papules and geographic site, volume injected, number of treatment sessions, subject characteristics at baseline (Fitzpatrick skin type, age and race), or baseline WAS (pre-injection, before first treatment).

Post Marketing Surveillance

The adverse events received from post-marketing surveillance (voluntary reporting and published literature) for SCULPTRA and SCULPTRA Aesthetic in the US and other countries include: visible papules/nodules with or without inflammation or discoloration, lack of effect, swelling, mass formation/induration, pain/tenderness, granuloma (including ectropion)/foreign body reaction, visual disturbance including transient blurred vision, reduced visual acuity, increased lacrimation, eyelid ptosis, dry eye and blindness, bruising/hematoma, erythema, nerve injury including paraesthesia, hypoesthesia and facial nerve paralysis, induration, bacterial infections and abscess formation, inflammation, skin discoloration, injection site reactions including burning sensation, warmth and irritation, atrophy/scarring, pruritus, deformity/facial asymmetry, rash, hypersensitivity/allergic reaction and angioedema, dermatitis, bleeding, symptoms of reactivation of herpes infection, urticaria, vesicles/blisters/pustules, ischemia/necrosis, acne, device dislocation, telangiectasia, discharge, and other dermatological events including alopecia, skin wrinkling, skin tightness, skin dryness, skin hypertrophy and photosensitive reaction, and non-dermatological events including headache, pyrexia, malaise, arthralgia, anxiety, nausea, insomnia, dyspnoea, fatigue, dizziness, muscular weakness or twitching, lymphadenopathy and depression.

Scarring, mostly a non-serious event, has been reported in association with skin discoloration, nodules, lumps, indurations, granulomas, hyperpigmentation, hypertrophic scars, and suspicion of keloid formation. Time to onset when specified ranged from within 1 week to 24 months post-Sculptra injection and outcome ranged from 'recovered' to 'on-going' at last contact.

Skin discoloration has been reported as a non-serious event, typically reported in association with lumps and nodules. It has also been reported with blanching and telangiectasias. Time to onset when specified usually ranged from within 1 week to 12 months post-injection. Outcome ranged from 'recovered' to 'on-going' at last contact.

Serious adverse events have rarely been reported. Reported serious adverse events for SCULPTRA and SCULPTRA Aesthetic with a frequency greater than 5 reported events include papule/nodule, swelling/edema, pain, granuloma, symptoms of visual disturbance, infection/abscess, mass/induration, paraesthesia and facial nerve paralysis, erythema, inflammation, bruising/hematoma, discoloration, deformity, scaring/atrophy, hypersensitivity, pruritus, rash, muscle disorders, ischemia/necrosis, urticaria and blisters.

When required, depending on event, treatments may include massage/manipulation, warm compress, nitroglycerine paste, corticosteroids, antibiotics, antihistamines, NSAIDs, aspiration/drainage of the product, saline injections and surgery. Events which did not resolve or where resolution information is not available at last contact were reported.

- Injection site nodules mostly occurred several months post-injection. Such nodules are occasionally associated with inflammation or discoloration, with time to onset ranging from 1-2 months to 14 months post-last injection. In some cases, the nodules were reported to resolve spontaneously or following treatment with e.g. intralesional corticosteroids; others have been described with a prolonged duration of up to 2 years. For those nodules that were larger in size, occurring in difficult anatomical regions (e.g. lower eyelid) or persisted after other treatments such as intralesional corticosteroids failed, surgical excision of the nodules was required.
- Granulomas usually occur several months after injection, in few cases onset was more than 1 year post-injection. While events were reported as granuloma, biopsy confirmation was made on few cases. Treatment ranged from subcision or intralesional corticosteroid with subsequent improvement, to surgical extraction. Of the few granuloma cases that required hospitalization, these were associated with infraorbital use or injection in the lip vermilion.
- Serious edema has been reported in association with erythema, pain, and heat sensation. The symptoms were mostly temporary, and with no significant impact on the quality of daily life reported. Treatment included corticosteroids, antihistamines and/or anti-inflammatories. Recovery occurred within 7-10 days without sequelae.
- Vascular compromise may occur due to an inadvertent intravascular injection or as a result of vascular compression associated with implantation of any injectable product. This may manifest as blanching, discoloration, necrosis or ulceration at the implant site or in the area supplied by the blood vessels affected; or rarely as ischemic events in other organs due to embolisation. Isolated rare cases of ischemic events affecting the eye leading to visual loss, and the brain resulting in cerebral infarction, following facial aesthetic treatments have been reported. Visual disturbances including blindness have been reported following injection of SCULPTRA or SCULPTRA Aesthetic into the temple area, periorbital areas, and/or cheek. Events requiring medical intervention, and events which did not resolve or where resolution information is not available were reported.
- Serious erythema, serious pain, and serious pruritus reported with bruising and heat sensation, were reported within 24 hours post-injection. Treatment included corticosteroids, anti-histamines and/or anti-inflammatories. Events resolved within 7-10 days post-injection without sequelae and with no significant impact on daily life.
- Serious hypersensitivity reactions have been reported mainly in association with facial swelling and Quincke's edema, with symptoms appearing from 1 day to 1 week post-injection. Patients recovered without sequelae after treatment with intravenous corticosteroids and antihistamines.
- Serious infections such as subcutaneous abscesses, cellulitis, folliculitis, and methicillin-resistant *Staphylococcus aureus* at the injection site, have been reported. Time to onset of event ranged from 1 day to one week. Of these cases a few required hospitalization with administration of intravenous antibiotics. All patients recovered or were recovering at the last contact.

CLINICAL STUDIES

A. Study Design

Controlled Phase Study (0-13 Months):
The safety and effectiveness of SCULPTRA Aesthetic use to correct WAS 2 (shallow) to 4 (deep) nasolabial fold wrinkles was evaluated in a randomized, multicenter, evaluator blinded, controlled study of otherwise healthy and immune-competent, as well as not pregnant or breast-feeding subjects with previously untreated nasolabial fold wrinkles and WAS of 2 through 4.

The subjects received bilateral injections of either SCULPTRA Aesthetic or Cosmoplast in both nasolabial fold wrinkles during a maximum of 4 sessions over 9 weeks. Study treatment was planned to be stopped when both nasolabial fold wrinkle reached optimal correction of WAS equal to 1 or 0, or until the maximum of 4 treatment sessions were completed.

The study subjects recorded adverse events in a subject diary after each treatment visit, and were followed by investigators at Week 3 and Months 3, 6, 9, and 13, after the last injection session. Standardized photographs were taken at screening, before each injection session and at each follow up visit.

Extension Phase Study (13-25 Months):
Study subjects who had received SCULPTRA Aesthetic were followed for safety and efficacy at months 19 and 25 after the last injection session. Standardized photographs were taken at each follow-up visit.

B. Study Endpoints

Controlled Phase Study (0-13 Months):
The primary efficacy endpoint was defined as the difference between SCULPTRA Aesthetic and control cohorts on the mean change from baseline in the WAS of the nasolabial folds at the 13 month follow-up time point as determined by the Blinded Evaluation Committee (BEC). Evaluation was based on the 6-point photo-numeric Wrinkle Assessment Scale (see INSTRUCTIONS FOR USE)

Optimal correction was defined as a WAS of 0 or 1.

Secondary effectiveness endpoints were: 1) Mean change from pre-treatment baseline in the WAS as determined by the BEC at the non-primary follow-up time points (Week 3 and Months 3, 6, 9, following the last treatment); 2) Treatment success rate defined as the proportion of patients with a photographic WAS of <2 as defined by the BEC at each follow-up time point; 3) Investigator/Subject Global Assessments (4= Excellent Improvement, 3= Much Improved, 2= Improved, 1= No Change, 0= Worse) and the Subject Satisfaction Scores (4= Excellent, 3= Very Good, 2= Good, 1= Satisfactory, 0= Not Satisfied) at each follow-up time point compared between treatments; and 4) Time to peak correction, defined as the length of time between pre-treatment baseline and the first time point at which the best score assessed by the BEC was obtained over the length of the follow up period. Degree of peak correction was also assessed.

Extension Phase Study (13-25 Months):
All secondary effectiveness endpoints described above were evaluated for the long- term extension study time points at 19 and 25 months.

C. Study Population

Controlled Phase Study (0-13 Months):
A total of 233 subjects (age 26 to 73 years) were randomized and treated. At the conclusion of 13 months 106 out of 116 SCULPTRA Aesthetic subjects and 111 out of 117 control subjects completed the controlled phase of the study. Demographics are outlined in Table 5.

Extension Phase Study (13-25 Months):
One hundred and six subjects, who had received SCULPTRA Aesthetic and completed the controlled phase study, entered the extension phase. The demographic and background characteristics of all subjects were similar to the overall population randomized in the controlled phase study.
At the end of the 25 month follow-up phase, 95 out of 106 of the subjects completed (see Table 5).

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

A PATIENT'S GUIDE TO TREATMENT WITH SCULPTRA® Aesthetic

SCULPTRA Aesthetic
(injectable poly-L-lactic acid)

Please review this information carefully before beginning your SCULPTRA Aesthetic Treatment.
This guide is intended to help you become familiar with **SCULPTRA Aesthetic** 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 Aesthetic** and its clinical data from your physician. This information is also available on www.sculptraaesthetic.com. This information is not meant to replace information provided by your healthcare provider. You should always ask your healthcare provider about your treatment and care.

GLOSSARY

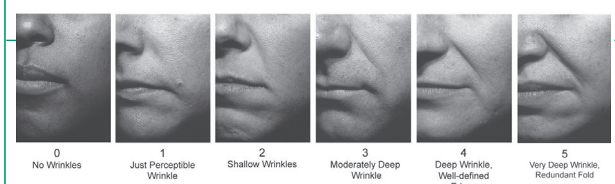
Anesthetic: A substance that causes loss of feeling or awareness. A topical or local anesthetic is a drug that causes temporary loss of feeling in a part of the body where it is placed.
Antiseptic: An agent that kills bacteria or prevents or slows growth of germs.
Biocompatible: A material that does 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.
Lipoatrophy: Loss of fat that is normally under the skin.
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.
Palpable: Able to be touched and felt.
Papule: Lump under the surface of the skin that is less than 5 mm and not visible, but can be felt when pressed.
Patient label: Product information for patients
Peri-orbital: Around the eye.
Poly-L-lactic acid: A man-made lactic acid polymer that is biocompatible and biodegradable.
Product label: Product information for healthcare providers
Side effect: An unwanted event caused by use of the product.
Wrinkle: age-related defect in the contour of the skin surface.
Wrinkle Assessment Score (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 AESTHETIC?

SCULPTRA Aesthetic 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 Aesthetic** 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 AESTHETIC?

SCULPTRA Aeshetic is intended for use in people with healthy immune systems as one-time treatment regimen of up to 4 injection sessions that are scheduled about 3 weeks apart for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate. **SCULPTRA Aesthetic** may provide cosmetic correction of facial wrinkles with a Wrinkle Assessment Score of 2, 3, or 4 as shown in the following photos (Figure 1):



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

WHO SHOULD NOT GET SCULPTRA AESTHETIC? (CONTRAINDICATIONS)

You should not get **SCULPTRA Aesthetic** if you:

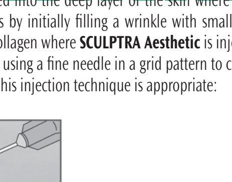
- Are allergic to any ingredient of **SCULPTRA Aesthetic**: "poly-L-lactic acid" (PLLA), carboxymethylcellulose (USP) or non-pyrogenic mannitol (USP).
- Previously had or have risks factors for hypertrophic scarring or keloid formation.

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

HOW DOES SCULPTRA AESTHETIC 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 Aesthetic** is injected into the deep layer of the skin where collagen naturally exists and is made. **SCULPTRA Aesthetic** works by initially filling a wrinkle with small PLLA beads. As the beads biodegrade the body may produce new collagen where **SCULPTRA Aesthetic** is injected. **SCULPTRA Aesthetic** is injected with multiple small injections using a fine needle in a grid pattern to correct a wrinkle at the nasolabial fold or other facial wrinkles where this injection technique is appropriate:



WHAT WERE THE RESULTS OF THE U.S. CLINICAL STUDY CONDUCTED ON SCULPTRA AESTHETIC?

A U.S. study was conducted to compare the safety and effectiveness of **SCULPTRA Aesthetic** 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 Aesthetic** (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 Aesthetic** 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 1 below.

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

SIDE EFFECTS TYPE *Immediate, as recorded in subject diaries*	116 Subjects 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

TABLE 5
STUDY POPULATION DEMOGRAPHICS

	Controlled Phase Study		Extension Phase Study
	SCULPTRA Aesthetic	Cosmoplast	SCULPTRA Aesthetic
Demographic	N (%)	N (%)	N (%)
Total study enrollment (randomized)	116	117	106
Age			
Mean (SD)	51.2 (7.8)	51.6 (8.4)	51.5 (7.9)
Gender			
Male	3 (2.6)	10 (8.5)	3 (2.8)
Female	113 (97.4)	107 (91.5)	103 (97.2)
Race			
Caucasian	96 (92.8)	89 (76.1)	86 (81.1)
Black	1 (0.9)	5 (4.3)	1 (0.9)
Asian	0	1 (0.9)	0
Hispanic	19 (16.4)	21 (17.9)	19 (17.9)
Other	0	1 (0.9)	0
Fitzpatrick skin type			
Type I	11 (9.5)	5 (4.3)	10 (9.4)
Type II	39 (33.6)	43 (36.8)	34 (32.1)
Type III	44 (37.9)	48 (41.0)	41 (38.7)
Type IV	16 (13.8)	15 (12.8)	16 (15.1)
Type V	5 (4.3)	4 (3.4)	4 (3.8)
Type VI	1 (0.9)	2 (1.7)	1 (0.9)
Nasolabial fold WAS before injection			
1	6 (5.2)	4 (3.4)	4 (3.8)
2	55 (47.6)	41 (35.3)	50 (47.2)
3	41 (35.3)	55 (47.6)	39 (36.8)
4	14 (12.1)	17 (14.7)	13 (12.3)
Total completed	**106**	**111**	**95**

D. Treatments Delivered

Controlled Phase Study (0-13 Months):

Treatment was planned for one to four sessions at 3 week intervals until optimal correction (WAS = 1 or 0) was achieved or four sessions were completed. At each treatment with SCULPTRA Aesthetic, multiple deep dermal injections in cross hatch grid pattern (see Figures 3 – 7 in the Instructions for Use) of 0.1-0.2 mL SCULPTRA Aesthetic (up to a maximum of 2.5 mL per nasolabial fold per session) were performed into the left and right nasolabial folds according to product Instructions for Use. At each treatment session with control multiple mid to deep dermal injections of an average of 1.0 mL Cosmoplast per nasolabial fold per session were performed into the left and right nasolabial folds according to product Instructions for Use. Table 6 presents the amount of Sculptra Aesthetic injected as a function of baseline wrinkle severity.

TABLE 6
SUMMARY SCULPTRA AESTHETIC AND CONTROL INJECTIONS

Baseline (Pre-Injection, before first treatment) WAS	1		2		3		4		ALL	
	Sculptra Aesthetic	Cosmo-plast	Sculptra Aesthetic	Cosmo-plast	Sculptra Aesthetic	Cosmo-plast	Sculptra Aesthetic	Cosmo-plast	Sculptra Aesthetic	Cosmo-plast
Number of pt injected (N)	6	4	55	41	41	55	14	17	116	117
Injection volume, mL										
Session 1										
n	6	4	55	41	41	55	14	17	116	117
Mean	4.4	2.7	4.0	2.8	4.2	3.3	4.0	3.5	4.1	3.1
Median	5.0	2.5	4.4	2.9	4.8	3.8	4.0	3.6	4.5	3.0
Range	2.0,5.0	2.0,4.0	1.5,5.0	1.4,4.0	1.7,5.0	0.9,6.0	2.6,5.0	1.0,6.0	1.5,5.0	0.9,6.0
Session 2										
n	5	3	52	28	39	47	14	16	110	94
Mean	3.7	1.9	3.3	1.8	3.8	2.2	3.9	2.2	3.5	2.1
Median	4.0	2.0	3.5	1.8	4.0	2.0	4.0	1.9	3.8	2.0
Range	2.0,5.0	1.6,2.0	1.4,5.0	0.9,4.0	0.4,5.0	0.9,4.0	2.7,5.0	0.6,5.0	0.4,5.0	0.6,5.0
Session 3										
n	4	1	32	18	35	30	14	11	85	60
Mean	3.4	3.0	3.0	1.6	3.4	2.0	4.0	2.0	3.3	1.9
Median	3.8	3.0	3.0	1.4	3.5	2.0	4.2	1.9	3.5	2.0
Range	1.6,4.5	3.0,3.0	0.8,5.0	0.8,4.0	0.9,5.0	0.5,5.0	2.0,4.6	0.6,4.0	0.8,5.0	0.5,5.0
Session 4										
n	3	1	18	8	25	17	13	6	59	32
Mean	3.5	2.0	3.4	1.3	3.3	2.0	4.1	1.2	3.5	1.7
Median	3.4	2.0	3.7	1.0	3.3	2.0	4.0	1.0	3.7	2.0
Range	3.0,4.0	2.0,2.0	1.5,5.0	0.5,2.6	1.0,5.0	0.4,4.0	3.0,5.0	0.5,2.0	1.0,5.0	0.4,4.0
Total Volume Injected, mL										
Mean	11.5	5.4	9.9	5.0	12.7	6.9	15.7	7.3	11.7	6.2
Median	11.9	4.3	8.8	4.5	13.3	5.5	15.9	5.8	11.5	5.0
Range	4.7,17.9	4.0,9.0	4.5,18.2	1.6,14.0	2.8,20.0	1.8,16.0	11.7,19.0	2.7,16.0	2.8,20.0	1.6,16.0
Number of sessions										
Total Number of Sessions	18	9	157	95	140	149	55	50	370	303
Mean Number of Sessions	3	2.3	2.9	2.3	3.4	2.7	3.9	2.9	3.2	2.6
Range	1.0,4.0	1.0,4.0	1.0,4.0	1.0,4.0	1.0,4.0	1.0,4.0	3.0,4.0	1.0,4.0	1.0,4.0	1.0,4.0

The mean total volume injected per subject was 11.7 and 6.2 mL for SCULPTRA Aesthetic and control treatments, respectively. The mean total volume injected per session, for both nasolabial folds, for SCULPTRA Aesthetic was 3.7 mL and 2.4 mL for control. A mean number of 3.2 and 2.6 injection sessions were required for SCULPTRA Aesthetic and control subjects, respectively to achieve WAS of 1 or 0, or until the maximum of 4 treatment sessions with 3 week interval was reached in the study population.

Extension Phase Study (13-25 Months):

Of the 106 subjects who entered the extension phase study, 105 (99%) did not receive any additional SCULPTRA Aesthetic treatments after optimal correction was achieved in the controlled study. One subject in the extension phase study received one treatment session of SCULPTRA Aesthetic at month 19.

EFFECTIVENESS RESULTS:

Controlled Phase (0-13 month) and Extension Phase (13-25 Months) Study Results:

Primary Effectiveness Endpoint -

The difference between SCULPTRA Aesthetic and control cohorts on the mean change from baseline in the WAS of the nasolabial folds at the 13 month follow up time point as determined by the Blinded Evaluation Committee was predicted to be 1.0 unit.

For the intended use population, Figure 1 demonstrates the observed WAS change from pre-treatment baseline through each treatment and follow-up point, individually for pre-treatment WAS = 2, 3, and 4. Table 7 presents the WAS change from pre-treatment baseline at each time point stratified by pre-treatment baseline score.

SCULPTRA Aesthetic (N=116) demonstrated improved WAS as compared to control (N=117) in correcting the contour deficiency of shallow (W=2) to deep (W=4) nasolabial folds at 13 months follow up after a single treatment regimen of up to four sessions of 2.5 mL maximum injections to the deep dermis with 3 week intervals. During the extension phase study (19 and 25 months follow up) SCULPTRA Aesthetic (N=106) continued to demonstrate improvements in WAS.

Figure 1

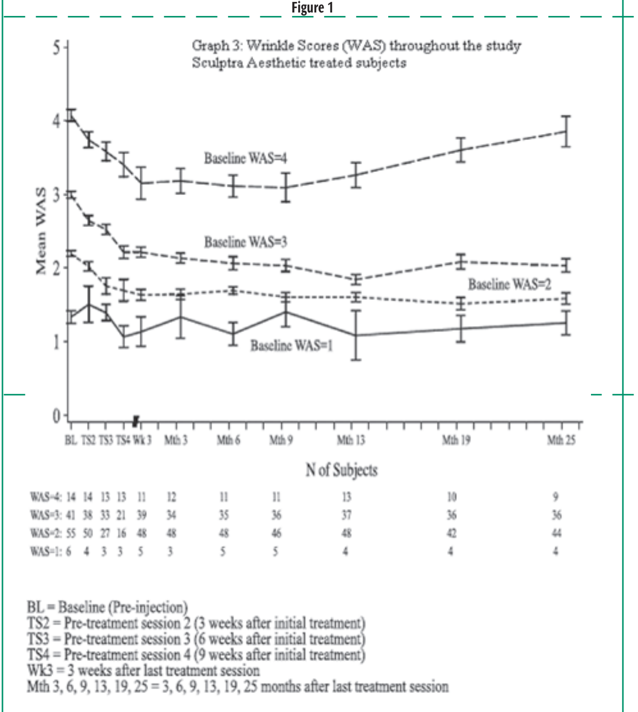


TABLE 7
WAS SUMMARY AT EACH TIME POINT STRATIFIED BY BASELINE SCORE
(Controlled and Extension Phase Study, 0-25 months)
Intent-to-Treat Population, SCULPTRA Aesthetic Subjects Only

Baseline WAS		Baseline *(Pre-Injection)*	Trt Session 2	Trt Session 3	Trt Session 4	Wk 3	Month 3	Month 6	Month 9	Month 13	Month 19	Month 25
1	N	6	4	3	3	5	3	5	5	4	4	4
	Mean (SE)	1.33 (0.086)	1.50 (0.245)	1.39 (0.111)	1.06 (0.147)	1.13 (0.200)	1.33 (0.289)	1.10 (0.155)	1.40 (0.201)	1.08 (0.337)	1.17 (0.180)	1.25 (0.160)
	Median	1.42	1.58	1.50	1.00	1.33	1.33	1.17	1.50	1.25	1.25	1.33
	Mean Change from Baseline (SE)	N/A	0.17 (0.236)	-0.06 (0.056)	-0.22 (0.056)	-0.17 (0.190)	-0.11 (0.242)	-0.27 (0.113)	0.03 (0.111)	-0.25 (0.220)	-0.17 (0.068)	-0.08 (0.048)
	P-Value for Change from Baseline	N/A	0.530	0.423	0.057	0.430	0.691	0.078	0.778	0.339	0.092	0.182
2	N	55	50	27	16	48	48	48	46	48	42	44
	Mean (SE)	2.19 (0.037)	2.02 (0.060)	1.75 (0.112)	1.69 (0.147)	1.63 (0.073)	1.64 (0.070)	1.69 (0.051)	1.60 (0.063)	1.60 (0.063)	1.51 (0.082)	1.58 (0.076)
	Median	2.17	2.00	1.83	1.92	1.67	1.67	1.83	1.50	1.67	1.50	1.58
	Mean Change from Baseline (SE)	N/A	-0.17 (0.057)	-0.46 (0.107)	-0.57 (0.145)	-0.53 (0.077)	-0.53 (0.071)	-0.50 (0.054)	-0.59 (0.062)	-0.59 (0.067)	-0.69 (0.084)	-0.61 (0.079)
	P-Value for Change from Baseline	N/A	0.005	<0.001	0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
3	N	41	38	33	21	39	34	35	36	37	36	36
	Mean (SE)	2.99 (0.043)	2.64 (0.065)	2.52 (0.067)	2.21 (0.084)	2.21 (0.068)	2.13 (0.066)	2.06 (0.088)	2.03 (0.084)	1.84 (0.068)	2.08 (0.098)	2.03 (0.090)
	Median	2.83	2.67	2.33	2.17	2.17	2.08	2.00	2.08	1.83	2.08	2.00
	Mean Change from Baseline (SE)	N/A	-0.37 (0.066)	-0.52 (0.053)	-0.83 (0.085)	-0.77 (0.069)	-0.83 (0.068)	-0.94 (0.083)	-0.97 (0.078)	-1.15 (0.065)	-0.94 (0.097)	-0.96 (0.089)
	P-Value for Change from Baseline	N/A	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
4	N	14	14	13	13	11	12	11	11	13	10	9
	Mean (SE)	4.07 (0.078)	3.74 (0.107)	3.58 (0.129)	3.40 (0.166)	3.15 (0.220)	3.18 (0.168)	3.11 (0.151)	3.09 (0.196)	3.26 (0.169)	3.60 (0.161)	3.85 (0.207)
	Median	4.08	3.67	3.67	3.33	3.17	3.17	3.17	3.00	3.17	3.75	3.83
	Mean Change from Baseline (SE)	N/A	-0.33 (0.103)	-0.49 (0.112)	-0.71 (0.145)	-0.92 (0.232)	-0.94 (0.167)	-1.02 (0.138)	-0.97 (0.194)	-0.85 (0.164)	-0.53 (0.108)	-0.31 (0.168)
	P-Value for Change from Baseline	N/A	0.007	<0.001	<0.001	0.003	<0.001	<0.001	<0.001	<0.001	<0.001	0.097

HOW SUPPLIED

SCULPTRA Aesthetic is supplied as a sterile freeze-dried preparation 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 Aesthetic contains two vials of poly-L-lactic acid, sodium carboxymethylcellulose (USP), non-pyrogenic mannitol (USP)

STORAGE

SCULPTRA Aesthetic can be stored at room temperature, up to 30ºC (86ºF). Upon reconstitution, SCULPTRA Aesthetic can be stored for up to 72 hours at temperatures between 5-30ºC. DO NOT FREEZE. Refrigeration is not required.

STERILITY

Each vial of SCULPTRA Aesthetic is packaged for single-use only. Do not resterilize.

IF THE VIAL, SEAL, OR THE FLIP-OFF CAP ARE DAMAGED, DO NOT USE AND CONTACT GALDERMA LABORATORIES, L.P. FORT WORTH, TX 76177 USA 1-855-425-8722.

INSTRUCTIONS FOR USE

SCULPTRA Aesthetic has only been evaluated in immune-competent people as a single regimen for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate.

SCULPTRA Aesthetic use should be limited to use in a single regimen of up to four sessions with three week interval using the threading or tunneling technique in grid pattern (see Figures 3- 7) to inject a maximum of 2.5 mL of SCULPTRA Aesthetic per site into the deep dermis medial to the nasolabial fold contour deficiency.

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

- Sterile Water for Injection (SWFI), USP
- Single-use 5 mL sterile syringe
- Single-use 1 or 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 (such as alcohol)

Reconstitution

SCULPTRA Aesthetic 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 is damaged, do not use, and call Galderma Laboratories, L.P. at 1-855-425-8722.
2. Attach an 18 G sterile needle to a sterile single-use 5 mL syringe.
3. Draw 5 mLs of SWFI into the 5 mL syringe.
4. Introduce the 18 G sterile needle into the stopper of the vial and slowly add all SWFI into the vial.
5. Let the vial stand for at least 2 hours to ensure complete hydration; do not shake during this period. Upon reconstitution, SCULPTRA Aesthetic can be stored for up to 72 hours at temperatures between 5-30ºC. Refrigeration is not required.
6. Product should be gently agitated immediately prior to use. Agitate the vial until a uniform translucent suspension is obtained. A single vial swirling agitator may be used. The reconstituted product is usable within 72 hours of reconstitution. As it is a single use vial, discard any material remaining after use or after 72 hours following reconstitution.
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 or 3 mL sterile syringe. Do not store the reconstituted product in the syringe.
8. Replace the 18 G needle with a 26 G sterile needle before injecting the product into the deep dermis. Do not inject SCULPTRA Aesthetic 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 Counseling**

It is necessary to counsel the patient and discuss the appropriate indication, risks, benefits and expected responses to the SCULPTRA Aesthetic treatment. Advise the patient of the necessary precautions before commencing the procedure.

- Before treatment with SCULPTRA Aesthetic, a patient should be provided patient labeling and completely informed by the treating physician of the intended use, indications for use, as well as the contraindications, warnings and precautions for use, expected correction, and possible side effects and mode of administration of SCULPTRA Aesthetic. Each patient should be informed that the amount of SCULPTRA Aesthetic and the number of injection sessions will depend on the patient's need.
- A treatment session to correct WAS 2 - 4 contour deficiencies (see picture, Figure 2) of facial wrinkles such as nasolabial folds consist of multiple deep dermal threading or tunneling injection of 0.1-0.2 mL of SCULPTRA Aesthetic in grid pattern to a maximum of 2.5 mL per nasolabial fold per session.

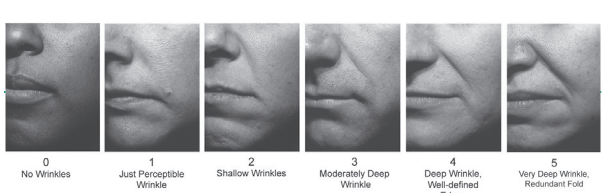


Figure 2

- One to four treatment sessions (typically three) might be needed to achieve optimal correction with a minimum of three week intervals between injection sessions.
- Patients should be informed that typically, at the end of the injection session, they will experience some degree of swelling due to the water (SWFI) used to reconstitute SCULPTRA Aesthetic and this will give the appearance of a full correction by the end of the injection session.
- Patients should be informed that the injection-related swelling typically resolves in several hours to a few days, resulting in the reappearance of the original contour deficiency.
- Patients should also be informed that the optimal correction after initial injection depends on patient's pre-treatment nasolabial fold WAS score. In the clinical study, optimal correction at 9 weeks after initial injection was most commonly found to be a 0.5 to 1 point decrease in WAS.
- Patients should be informed that, if needed, their physician may utilize a topical or a local anesthetic prior to injecting SCULPTRA Aesthetic.

2. **Patient Assessment**

- A complete medical history should be taken to determine if SCULPTRA Aesthetic injection is appropriate. Using the standard wrinkle assessment score (WAS) photographs provided for patient counseling, a patient should be informed of the optimal cosmetic correction that may be expected by that patient, and that up to four injection sessions (typically three) may be needed to achieve the desired results.
- During the initial treatment session with SCULPTRA Aesthetic, only a limited correction should be made. In contrast to other wrinkle fillers, SCULPTRA Aesthetic provides a gradual improvement of the depressed area over several weeks as the treatment effects occur.

3. **Patient Preparation**

Each injection session is to be conducted with aseptic technique and universal precautions due to the potential for contact with patient body fluids: blood from the injection site. Before injecting SCULPTRA Aesthetic a treatment plan is determined and the face mapped. The mapping is done using a water soluble pencil and a grid that is parallel and perpendicular to the nasolabial fold is outlined. See Section 6 - Injecting: Threading or Tunneling Technique.

4. **Injection Needle**

SCULPTRA Aesthetic should be injected using a sterile 26 G needle. SCULPTRA Aesthetic should not be injected with needles with a diameter smaller than 26 G or needles that have been bent. To maintain a uniform suspension throughout the procedure, intermittently agitate SCULPTRA Aesthetic in the syringe. Before initial injection, expel a few drops of SCULPTRA Aesthetic through the attached 26 G needle to eliminate air and to check for needle blockage. If the needle becomes occluded or dull during an injection session needle replacement is necessary. If clogging occurs, remove the needle, expel a small amount of product, attach a new sterile 26g needle, then expel a few drops of SCULPTRA Aesthetic to eliminate the air and re-check for needle blockage.

5. **Depth of Injection**

SCULPTRA Aesthetic should be injected into the deep dermis with tunneling (threading) technique.

As per Figure 7, SCULPTRA Aesthetic should be injected into tissue that is medial to the nasolabial fold wrinkle defect.

To guide the needle to the deep dermal plane, create a firm needle insertion plane by stretching the skin (Figure 3).

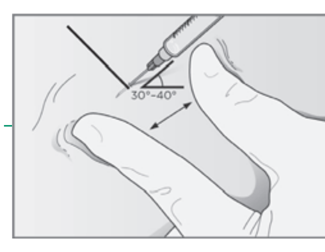


Figure 3

Introduce a straight, sterile, bevel-up 26 G needle into the skin at an approximately 30-40 degree angle to the skin and then advance the needle to the deep dermis until the desired skin depth is reached (Figure 4).

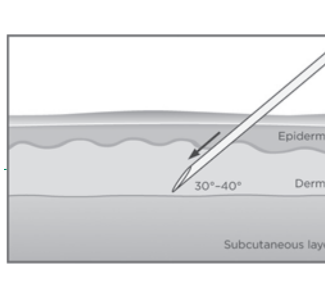


Figure 4

A change in tissue resistance is felt when the needle crosses from the dermis into subcutaneous layer. If the needle is inserted at too shallow (small) an angle or if the needle tip is not sufficiently advanced, then the needle tip may be in the mid or superficial (papillary) dermis, the needle bevel may be visible through the skin. If SCULPTRA Aesthetic is injected too superficially, the injected area will blanch immediately or shortly after injection. If the injected area blanches, remove the needle and massage the area in a circular fashion. Blanching may represent a vessel occlusion. If normal skin coloring does not return, do not continue with the injection. In the event that the blanching does not disappear, the patient should not be re-injected.

6. **Injecting: Threading or Tunneling Technique in a Grid Pattern (cross-hatch)**

a. **Technique**

When the needle tip is in the deep dermal plane, the needle angle should be lowered to 10-20 degrees and the needle should be advanced in the deep dermal plane parallel to the surface of the skin (Figure 5).

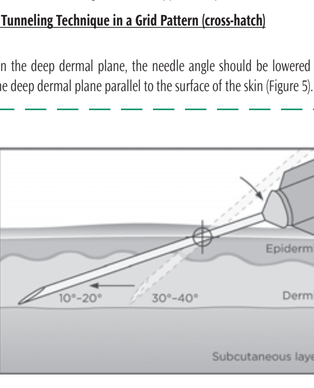


Figure 5

Before injecting SCULPTRA Aesthetic, always perform a reflux maneuver to avoid intravascular injection. If blood returns to the syringe, the needle is in a blood vessel and should be withdrawn, pressure should be applied to the injected area until bleeding stops and a new syringe should be prepared. If no blood is pulled back into the syringe, use the threading or tunneling technique, to deposit a thin trail of SCULPTRA Aesthetic by doing a retrograde injection when slowly withdrawing the needle (Figure 6).

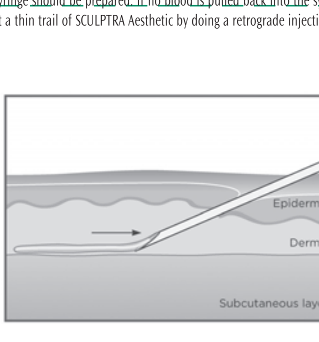


Figure 6

Based on the treatment plan (see Section 3 - Patient Preparation), Start the first injection at the base of the nasolabial fold. After completing the length with injections parallel to the nasolabial fold, the cross-hatch pattern is achieved with additional injections perpendicular to the first injection. Picture below shows a cross-hatch pattern after completing the last injection (Figure 7).

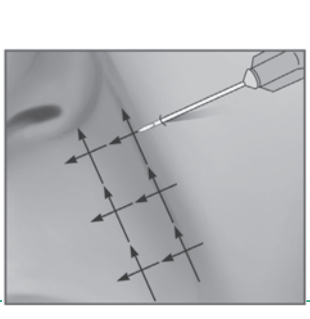


Figure 7

b. **Volume per Injection**

The maximum volume of SCULPTRA Aesthetic per individual injection should be limited to 0.1 mL – 0.2 mL, spaced at a distance of 0.5 -1 cm. Avoid overcorrection.

c. **Volume per Treatment Site**

A treatment session to correct WAS 2 - 4 nasolabial fold contour deficiencies consists of multiple deep dermal threading or tunneling injection of 0.1-0.2 mL of SCULPTRA Aesthetic in grid pattern to a maximum of 2.5 mL per nasolabial fold per session. The volume of SCULPTRA Aesthetic per surface area of injection grid has not been determined. During the initial treatment sessions only a limited correction should be made. In contrast to other wrinkle fillers, SCULPTRA Aesthetic provides a gradual correction of a contour deficiency over several weeks.

7. **Massage During the Injection Session**

The treatment area should be massaged in a circular fashion after every 3-4 injections to evenly distribute the product.

8. **Degree of Correction**

The contour deficiency should be under-corrected, never fully corrected or overcorrected (overfilled) during any injection session. Under-correction of the treatment area allows for gradual improvement of the contour deficiency as the SCULPTRA Aesthetic effect occurs over the minimum of three weeks between assessment and possible next injection session.

9. **Post-treatment Care**

Immediately after a SCULPTRA Aesthetic injection session, redness, swelling, and/or bruising may appear in the treatment area. See ADVERSE EVENTS for details of the incidence and severity of adverse event observed immediately post-injection during the clinical trial. To help SCULPTRA Aesthetic distribute evenly in the contour deficiency, it is important at the end of the treatment session to manually massage in a circular fashion the treatment area for a minimum of 2 minutes. A facial moisturizer should be used to perform the massage.

It is recommended that the patient should massage the treated areas for five minutes, five times per day for five days after the injection session to promote a natural-looking correction. To reduce the risk of edema and/or bruising after injection, an ice pack (avoid any direct contact of the ice with the skin) is applied to the treated areas.

Early occurrence of subcutaneous nodules at the injection site (within 3 to 6 weeks after the treatment) may be minimized by adhering to proper dilution and injection techniques (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. Nodules usually resolve spontaneously. However, as reported in published literature, some nodules may require medical treatment such as subcision (break-up of nodules with sterile saline solution), and delayed occurrence of subcutaneous nodules at the injection site (usually will manifest within 3 to 4 months after the treatment) may require treatment such as intralesional injections of corticosteroids, subcision and/or excision.

10. **Treat, Wait, Assess**

During the first injection session with SCULPTRA Aesthetic, only a limited correction should be made. The contour deficiency should be under-corrected, never fully corrected or overcorrected (overfilled) during any injection session. Re-evaluate the patient no sooner than three weeks after the injection session to determine if additional correction is needed. The patient should be advised before and after an injection, that typically at the end of the injection session, it is expected to experience some degree of swelling associated with the injection procedure itself. This will give the appearance of a full correction by the end of the injection session and this injection-related swelling typically resolves in several hours to a few days. For this reason, the original contour deficiency may initially reappear, but the deficiency is expected to gradually improve within several weeks of SCULPTRA Aesthetic injection as the effect occurs. The patient should be advised of the potential need for up to four injection sessions (typically three) at the first consultation.

PATIENT INSTRUCTIONS

It is recommended that the following information is shared with patients by the healthcare provider:

- To report any adverse reactions, call Galderma Laboratories, L.P. at 1-855-425-8722.
- Within the first 24 hours, an ice pack (avoiding any direct contact of the ice with the skin) should be applied to the treatment area to reduce swelling and bruising. SCULPTRA Aesthetic may cause redness, swelling, or bruising when first injected into the skin, typically resolving in hours to one week. Hematoma may also occur, typically resolving in hours to about two weeks. Worsening or prolonged symptoms or signs should be reported to the health care provider. The original skin depression may initially reappear, but the depression should gradually improve within several weeks as the treatment effect of SCULPTRA Aesthetic occurs. The health care provider will assess the need for additional SCULPTRA Aesthetic injection sessions after at least three weeks.
- It is recommended to massage in a circular fashion the treated areas for 5 minutes, 5 times per day for 5 days following any injection session, according to the physician's advice.
- Treatment with SCULPTRA Aesthetic can result in small papules in the treated area. These subcutaneous papules are typically not visible and asymptomatic and may be noticed only upon pressing on the treatment area. However, visible nodules, sometimes with redness or color change to the skin, have been reported. Patients should report these events and any other side effects to their health care provider.
- Aesthetic make-up may be applied a few hours post-treatment if no complications are present.
- Exposure of the treated area to sun and UV lamp exposure are to be avoided until any initial swelling and redness has resolved. Patients should be informed about appropriate sunscreen protection according to the physician's advice.

ANY SIDE EFFECTS, ADVERSE EVENTS, PRODUCT QUESTIONS OR PRODUCT COMPLAINTS SHOULD BE REPORTED TO:
Galderma Laboratories, L.P. Fort Worth, TX 76177 USA 1-855-425-8722

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Distributed by:
Galderma Laboratories, L.P.
14501 N. Freeway
Fort Worth, TX 76177 USA

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

Results showed that **SCULPTRA Aesthetic** 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.

WHAT ADVERSE EVENTS HAVE BEEN REPORTED THROUGH VOLUNTARY POST-MARKETING SURVEILLANCE OF SCULPTRA AND SCULPTRA AESTHETIC 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 Aesthetic** 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 health care practitioner immediately.

ARE SKIN TESTS NEEDED BEFORE TREATMENT WITH SCULPTRA AESTHETIC?

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

ARE THE RESULTS FROM SCULPTRA AESTHETIC IMMEDIATE?

No. Unlike other wrinkle fillers, **SCULPTRA Aesthetic** provides a gradual improvement of the depressed area over several weeks as the treatment effects occur. During the initial treatment session with **SCULPTRA Aesthetic**, a contour defect 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 Aesthetic**. This usually resolves in several hours to a few days and may cause the original wrinkle to reappear: you may look as you did before your treatment. Visible wrinkle correction results appear slowly. Your healthcare provider should see you again in three or more weeks to decide if you need additional injections.

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

Your healthcare provider should see you at approximately three 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 Aesthetic** has only been studied in a single treatment regimen of up to four sessions at three week intervals.

HOW LONG DO SCULPTRA AESTHETIC 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 nasolabial fold wrinkle (WAS score) that a subject had before treatment. Discuss with your health care provider the optimal cosmetic correction you may expect.

DO INJECTIONS OF SCULPTRA AESTHETIC HURT?

As with any injection, to decrease pain during injection, a topical or a local anesthetic may be applied to the injection area skin before injecting **SCULPTRA Aesthetic**. In 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 provider will answer all of your questions and ask about your medical history to determine if **SCULPTRA Aesthetic** injection is appropriate for you. Tell your healthcare provider about all the medicines you are taking, even over the counter medicines or treatments. You and your healthcare provider 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 Aesthetic** will be injected in multiple small amounts into the skin using a fine needle in grid pattern.
- After injection, the treated area should be massaged to distribute the product evenly.
- An ice pack should be applied to the treatment area to help reduce swelling unless otherwise directed by your healthcare provider.

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 STUDY" and "REPORTS THROUGH VOLUNTARY POST-MARKET SURVEILLANCE". Your healthcare 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 sun and UV sun lamp exposure until swelling and redness have disappeared
- Report any worsening or longer-lasting signs of symptoms to your healthcare provider.
- 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 physician 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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