GALDERMA

SCULPTRA®

Poly-L-lactic acid

en INSTRUCTIONS FOR USE

Instructions for Use, Patient Information and Training on administration and safe use are available at: www.galderma.com/library

Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.

Description

Sculptra is a poly-L-lactic acid implant which is reconstituted from a sterile dry powder by the addition of sterile water for injection to form a suspension. Poly-L-lactic acid is biocompatible and biodegradable. Sculptra is produced by aseptic manufacturing and supplied in a clear glass vial. To provide pain relief during the injection procedure, a sterile lidocaine hydrochloride solution may be added to the vial of reconstituted product prior to injection. Each Sculptra vial is for single patient and single session use only. For each Sculptra vial, a Patient Information and an Implant Card for the patient are provided. To ensure traceability, patient record labels are also provided and should be attached to patient records.

Composition

Each vial of dry powder contains:

Poly-L-lactic acid[1)]	150 mg
Sodium carboxymethylcellulose	90 mg
Mannitol	127.5 mg

[1)] The Poly-L-lactic acid has a median particle size of approximately 50 µm (laser diffraction technique), and an inherent viscosity of 0.7-1.1 dL/g (capillary viscometry). The inherent viscosity is an indirect measure of the molar mass of the Poly-L-lactic acid.

Intended purpose

Sculptra is for aesthetic use to increase the volume of depressed areas of the face and body, particularly to correct skin creases, wrinkles, folds, cellulites, and for skin quality improvements.

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

Indications

For use in the nasolabial folds, cheeks, marionette lines, temples, chin crease, décolletage, gluteal area, posterior thighs and upper arms.

Patient target group

Sculptra is for use in adult patients only. Do not use Sculptra in patients under 18 years of age. For pregnant or breastfeeding females, the safety for use has not been established.

Intended users

Sculptra is only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law. Ensure that you fully understand the conditions to safely and properly use the product. Contact your local Galderma representative or Sculptra distributor for more information about preparation procedure, injection techniques and training opportunities.

Performance Characteristics

Sculptra, when prepared with sterile water for injection, consists of a suspension of solid poly-L-lactic acid microparticles. When injected, the suspension provides a gradual soft tissue augmentation and skin thickening, over the course of a few weeks, as the microparticles are surrounded by host connective tissue with a build-up of new collagen and elastin fibers, reducing signs of skin aging. Early onset of tissue response was shown in a pre-clinical 3D skin model with increased epidermal thickness after 5 and 14 days. It is for aesthetic use with no intended medical purpose.

Individual variation and treatment area may affect the biodegradation of this product. The product gradually breaks down and disappears within 18 months or longer. Product remnants were detected in skin biopsies up to 28 months after injection. Thus, adverse events such as inflammatory reactions, nodules and granulomas may occur with late onset.

Sculptra was studied in several randomized controlled and open-label clinical trials for a variety of indications in facial and non-facial areas. The follow-up time was up to 5 years. Studies have demonstrated a long-lasting (≥2 years) aesthetic improvement and high patient and investigator satisfaction. The overall safety profile showed that Sculptra was well-tolerated.

Summary of Safety and Clinical Performance (SSCP)

The SSCP is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI:

https://ec.europa.eu/tools/eudamed

Basic UDI-DI: 73316890138V

Contraindications

- Do not use in patients with a history of hypersensitivity to any of the constituents to the product.
- Do not use in patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
- Do not use the suspension supplemented with lidocaine in patients with a history of hypersensitivity to lidocaine or other amide-type local anesthetics.
- Do not use when there is an underlying known active systemic disease or there is active disease, such as inflammation (skin eruption such as cysts, pimples, rashes or hives), infection or tumors, in or near the intended treatment site, until the underlying process has been controlled.

WARNINGS

- Improper injection techniques such as superficial placement, excessive amount of product or incorrect preparation procedure may lead to appearance of papules or nodules at the injection site. Massage the treatment area to ensure proper distribution of the product to minimize the appearance of such papules or nodules.
- Do not inject intramuscularly or in tendons. This could result in hematoma and pain in the affected area.
- Do not inject intravascularly. Aspiration prior to each injection is recommended. Localized superficial ischemia and necrosis with potential scarring may occur after injection in or near blood vessels, especially in areas with limited collateral blood flow. This may be caused by the injury, obstruction, or compromise of blood vessels. Use additional caution if the patient has undergone a prior surgical procedure or had previous trauma to the planned treatment area.
- Unintentional introduction of soft tissue fillers into the vasculature may lead to embolization, occlusion of the vessels, ischemia, necrosis or infarction at the implant site or in the area supplied by the blood vessels affected. Rare but serious adverse events include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage leading to stroke, skin necrosis, and damage to underlying structures. Immediately stop the injection if any of the following symptoms occur, 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 healthcare professional specialist, should an intravascular injection occur.
- Use with caution in patients with bleeding disorders or patients using substances that affect platelet function, thrombolytics or anticoagulants. These patients may experience increased bruising, or bleeding at the injection site.
- Do not overcorrect (overfill) a contour deficiency, because the depression should gradually improve within several weeks as the treatment effect of Sculptra occurs. If an overcorrection occurs, the area concerned should be thoroughly massaged to ensure proper distribution of the product.
- Do not inject into the red area of the lip (vermillion) or in the periorbital area.
- Always prepare the dry powder with sterile water for injection.

PRECAUTIONS

- This product should only be used by healthcare professionals who have adequate knowledge about the anatomy at and around the site of injection to minimize the risks of potential complications (such as formation of papules/ nodules, perforation or compression of vessels, nerves and other vulnerable structures such as parotid gland).
- Healthcare professionals 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.
- Follow aseptic technique and standard practice to prevent cross-infections. Injection procedures are associated with risk of infection.
- Use with caution in patients with autoimmune disease or in patients on immunosuppressive therapy.
- Use with caution in patients with risk factors for developing skin irritation as this may increase the risk for post-treatment skin reactions.
- Use with caution in patients with pre-existing tendency toward edema formation, as these patients may experience excessive swelling due to fluid build-up.
- Advise patients that inflammatory pigmentation changes and scarring might occur following soft tissue injections.

PRECAUTIONS *(continued)*

- Use with caution in patients with abnormal wound-healing and in patients with dark skin (Fitzpatrick Type IV–VI), as they may be more prone to hypertrophic scarring and keloid formation.
- Use with caution in patients with latent or subclinical herpes viral infections, as these may be reactivated by the injection procedure.
- Do not directly mix other filler products, drugs (other than lidocaine), or other substances, with Sculptra prior to injection. No studies of interactions of Sculptra mixed, or concomitantly administered, with such products have been made.
- Avoid injecting into areas with or in close proximity to prior implants other than Sculptra. Injecting into these areas could aggravate latent adverse events or interfere with the aesthetic outcome of the treatment.
- Avoid large bolus injections or injecting too superficially. This may result in contour irregularities and palpable lumps.
- Use caution when injecting in areas with limited soft tissue support, limited soft tissue cover or thin skin (e.g., décolletage or atrophic skin). This may lead to contour irregularities and palpable lumps. Injections in these areas should be performed in small volumes per injection.
- Avoid procedures based on active dermal response, including laser treatment or chemical peeling, before the skin has healed completely after treatment with Sculptra. This may lead to an inflammatory reaction at the implant site. This also applies if Sculptra is administered before the skin has healed completely after such a procedure.
- Advise patients to avoid excessive sun, UV lamp exposure and extreme temperatures until any initial swelling and redness has resolved.
- Advise patients that the implanted product might appear as an incidental finding on subsequent diagnostic imaging with ultrasound, MRI, CT scans and standard plain radiography. Sculptra is safe in a MR environment.
- Do not use the product if the package or vial is opened or damaged, as the sterility of the product may be compromised.
- Do not use the product if the expiration date or lot number is missing or illegible.
- Do not re-sterilize or reuse the product, as it may lead to risks of infection. Each Sculptra vial is for single patient and single session use only. Discard the vial and any remaining product immediately after use.
- After use, injection syringes and needles/cannulas should be handled as potential biohazards and disposed of as per applicable local and national requirements.
- Use care when handling the glass vial. If the vial is broken, carefully dispose of the broken glass to avoid laceration or other injury.

The following precautions should be observed if an optional 1 mL sterile 2% lidocaine solution is added to the suspension in the vial after reconstitution:

- Consider safety risks associated with the use of lidocaine, including possible toxic effects in patients with increased sensitivity such as epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.
- Consider that systemic toxic effects can be additive for lidocaine in the suspension and concurrently used lidocaine or other local anesthetics or agents structurally related to amide-type local anesthetics (e.g., certain anti-arrhythmics). The maximum safe dose of lidocaine is 4.5 mg/kg. For specific safety information, refer to the product labelling for the lidocaine solution used.

ADVERSE EVENTS

Adverse events have been reported in clinical investigations, literature, or voluntarily from worldwide sources post marketing, after treatment with Sculptra. Such adverse events may appear immediately or up to a year or more after the treatment.

Reports of serious adverse events are very rare and include nodules/papules, swelling, infection/abscess, mass and granuloma, visual impairment, and hypersensitivity reactions. When required, treatments for these events may include corticosteroids, antibiotics, antihistamines, analgesics, anticoagulants, nitroglycerine paste, aspiration/incision and drainage, hyperbaric oxygen or surgery.

For patients who have experienced clinically significant reactions, a decision for repeat treatment should take the cause and severity of previous reactions into consideration.

Most commonly reported adverse events:

Transient injection procedure-related reactions such as bruising/bleeding, pain/tenderness, swelling, erythema and pruritus at the implant site, with onset immediately or shortly after treatment. Typically, resolution is spontaneous within one week.

Subcutaneous nodules or papules, invisible but palpable, or visible in the injection area. Such nodules/papules mostly occur several weeks up to a year post-injection and are occasionally associated with inflammation or discoloration. They tend to occur most frequently in facial areas with high mobility such as perioral area (marionette lines) and periorbital area, or areas of thin skin (such as décolletage). Early occurrence of nodules/papules may be minimized by adhering to proper product preparation and injection techniques. Serious nodules usually have a 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 were 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 failed, surgical excision of the nodules was required.

Swelling or edema with onset up to several weeks or months after treatment. These events are commonly associated with a local inflammatory reaction and could include pain/tenderness, erythema, and pruritus, sometimes with a bacterial infection, including abscess formation, pustule, cellulitis and purulent discharge, and with asymmetry or deformity. In case of unexplained inflammatory reactions, infections should be excluded. Serious infections with abscesses are rarely reported with onset up to a week or a delayed onset up to a year following the injection. In case of persistent or recurrent inflammatory symptoms or infections, consider removal of the product by aspiration/drainage. Before any removal procedure is performed, the swelling or infection may be reduced by using a short course of corticosteroids or antibiotics, in order to palpate any remaining product more easily. More severe inflammation and infection events might result in skin atrophy and scarring.

Less commonly reported adverse events:

Implant site mass, induration, granulomas and foreign body reactions with potential associated encapsulation, with concurrent asymmetry and deformity, have been reported with a time to onset ranging from a month to a year or longer. Only a few cases of these granuloma cases were biopsy-confirmed. Treatment includes intralesional corticosteroid and in rare cases surgical extraction.

Hypersensitivity reactions with symptoms of erythema, dermatitis, urticaria, rash, blisters/vesicles, angioedema, etc., are often reported with immediate onset up to a few days following the injection. Serious hypersensitivity and anaphylactic reactions are rare.

Post-inflammatory hyper- or hypopigmentation, or other discoloration, following treatment is usually transient and resolves spontaneously. In general patients with Fitzpatrick skin types IV to VI or with wound-healing disorders are more prone to develop post-inflammatory hyperpigmentation and scarring following trauma. Keloid- or hypertrophic scarring are rarely reported.

Less commonly reported adverse events:
(continued)

Vascular compromise and vascular occlusion 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/pallor, discoloration, livedo reticularis, pain, necrosis or ulceration, and scab formation at the implant site or in the area supplied by the blood vessels affected; or in rare cases, as ischemic events or infarction in other organs due to embolization. Serious cases of local ischemic events with possible scarring and rare cases of temporary or permanent vision impairment, blindness, reduced visual acuity, retinal artery occlusion, cerebral ischemia, or cerebral hemorrhage leading to stroke, or pulmonary emboli, have been reported following use of Sculptra or following the use of other injectable aesthetic products. Prompt medical attention and evaluation by an appropriate healthcare professional specialist is recommended should an intravascular injection occur.

Other injection site reactions and skin reactions including burning sensation, exfoliation, dryness, irritation, discomfort, warmth and needle track marks and neurological symptoms including hypoesthesia, hyperesthesia, paresthesia and facial nerve paralysis.

Eye disorders including dry eyes, diplopia, eye irritation, eyelid edema, eye pain, eye swelling, eyelid ptosis, increased lacrimation and blurred vision.

Other rarely reported adverse events:

Acne, device dislocation, discharge, extravasation/compartment pressure symptoms, muscle disorders including muscle twitching, muscular weakness and muscle tightness, reactivation of herpes infection, capillary disorders such as telangiectasia, skin laceration, rosacea exacerbation, other dermatological events including localized alopecia, fibrosis, lipoma, skin disorder, skin tightness and skin wrinkling.

Non-dermatological events including anxiety/emotional distress, autoimmune reaction exacerbation, arthralgia, dysphagia, dyspnea/respiratory disorder, fatigue, headache, influenza-like symptoms, insomnia, lymphadenopathy, nasal congestion, nausea, oral disorder, parotitis/obstructive sialadenitis, pyrexia, presyncope, rhinorrhea, sinusitis and tinnitus.

Delayed-onset inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers. Cases of delayed-onset inflammation have been reported to occur at the dermal filler treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own.

Potential adverse events related to use of optional lidocaine hydrochloride solution

Commonly reported local adverse reactions in the skin: Paresthesia

Rarely reported: Hypersensitivity, urticaria, rash and angioedema

Systemic adverse reactions are unlikely based on the maximum dose of Sculptra. Possible signs of systemic toxicity will be similar in nature to those observed after administration of lidocaine as a local anesthetic agent, and may include dizziness, vomiting, drowsiness, seizures, mydriasis, bradycardia, arrhythmia, and shock. If signs of toxicity occur, immediately stop administration, and call for emergency medical assistance. See the labeling for the selected lidocaine hydrochloride solution for additional information.

Adverse events reporting

Contact your local Galderma representative or Sculptra distributor to report any incidents related to use of this product, including adverse events, product malfunction or potential quality issues. Report any serious incident to both your local Galderma representative or Sculptra distributor, and to your local competent authority.

SHELF LIFE AND STORAGE

Sculptra dry powder must be used prior to the expiration date indicated on the package.

- The dry powder should be stored at 15–30 °C.
- Upon reconstitution, the chemical and physical in-use stability of the suspension has been demonstrated for storage in the vial without addition of lidocaine up to 72 hours at refrigeration (2–8 °C) and at room temperature up to 30 °C. The suspension should be used immediately after reconstitution and may be stored in the vial (without lidocaine) at the healthcare professional's discretion only if aseptic technique was used to reduce the risk of microbiological contamination.
- The suspension should be used immediately after removal from the Sculptra vial.

In-use storage times and conditions are the responsibility of the healthcare professional.

TREATMENT PROCEDURE

General use conditions

- Prepare and inject the product in a clinical environment, such as a medical office.
- Use medical gloves and work under aseptic and hygienic conditions.
- Healthcare professionals are encouraged to identify a local ophthalmologist to be available in the event of an ophthalmic adverse event related to an unintentional intravascular injection.

Patient counseling and assessment

- Obtain the patient's medical history and treatment expectations, and palpate the treatment area to identify any abnormalities, for proper patient selection. Patients with unattainable expectations are not suitable candidates for treatment.
- Inform the patients about the indications, contraindications, warnings, precautions, treatment responses and potential adverse events.
- Each patient should be informed that the amount of Sculptra and the number of injection sessions will depend on the patient's need and the severity of the depressed area based on the mode of action of the product.
- Provide the patient with a copy of the enclosed Patient Information for review.
- Conduct vision assessments before and after treatment (including visual acuity, extraocular motility, and visual field testing) to assess the impact in the event of an unintentional intravascular injection.

TREATMENT PLANNING

A treatment cycle of four treatment sessions spaced at least four weeks apart is generally recommended. Evaluate the effect after each treatment session to assess the need for additional treatment. Because the treatment effects for Sculptra appear gradually over a few weeks, only a limited correction should be made at each treatment session.

Use the Treatment guide below to select the number of Sculptra vials and preparation volume for the treatment.

Do not exceed the maximum number of Sculptra vials for the treatment indication. Do not exceed a total number of 6 vials per session.

Prepare Sculptra for single patient use before each treatment session. Discard any unused Sculptra product immediately after the treatment session.

TREATMENT GUIDE

SCULPTRA PREPARATION STEPS	ANATOMICAL INDICATION					
	Facial use		**Non-facial use**			
	Face	Lipoatrophy	Décolletage	Upper arm	Gluteal area	Posterior thigh
Maximum number of Sculptra vials (**do not** exceed a total of 6 vials per session)	**2 vials**	**3 vials**	**2 vials**	**4 vials** (2 per arm)	**6 vials** (3 per buttock)	**6 vials** (3 per thigh)
Step 1 Reconstitution in the Sculptra vial	5 mL SWFI		5 mL SWFI	5 mL SWFI		
Step 2 Further reconstitution in the Sculptra vial	Up to 3 mL SWFI (optional)		3 mL SWFI	3 mL SWFI		
Step 3 Addition of lidocaine (optional)	1 mL lidocaine (optional)		1 mL lidocaine (optional)	1 mL lidocaine (optional)		
Step 4 Dilution in syringes	None		9 mL SWFI (optional)	9 mL SWFI		
Total preparation volume per Sculptra vial (with lidocaine)	**5-8 mL** (6-9 mL)		**8 or 17 mL** (9 or 18 mL)	**17 mL** (18 mL)		
Injection depth	Deep dermis, subcutaneous or supraperiosteal layer		Deep dermis, subcutaneous layer	Deep dermis, subcutaneous layer		

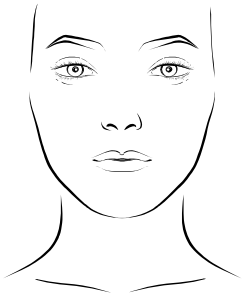
SCULPTRA PREPARATION PROCEDURES

Select the appropriate number of Sculptra vials and preparation volume using the **Treatment guide**.

Follow the steps below for each vial.

It is recommended to use the Sculptra suspension immediately after preparation.

Sculptra suspension should not be stored in the syringes.



5-9 mL
per Sculptra vial

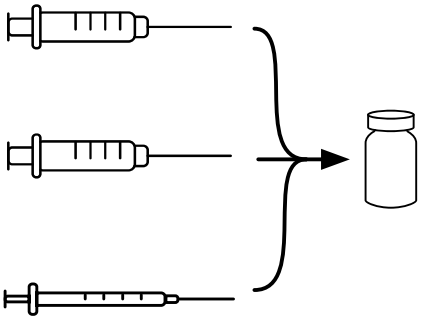
FACIAL USE

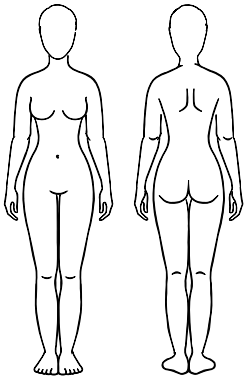
Reconstitution in the Sculptra vial

1 Step **+ 5 mL** SWFI

2 Step **+ 3 mL** SWFI

3 Step **+ 1 mL** lidocaine (optional)



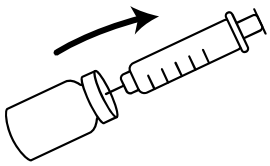


17-18 mL
per Sculptra vial

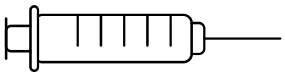
NON-FACIAL USE

Follow steps 1-3, then step 4 for **additional** dilution in syringe

4 Step Withdraw from vial



+ 9 mL SWFI
(in separate syringe)



Mix between syringes

1 Step RECONSTITUTION IN THE SCULPTRA VIAL

Recommended supplies:
- Antiseptic (such as alcohol)
- Sterile Water For Injection (SWFI)
- Single-use 5 mL sterile syringe
- 18G regular wall sterile needle

To reduce the risk of coring (damaging the stopper), do not use thin wall needles to penetrate the Sculptra stopper.

Use aseptic technique throughout the procedure.

Start with a clean work space and wear medical gloves.

Use only sterile, single-use supplies.

Clean the stopper of the Sculptra vial with an antiseptic. The stopper is not sterile under the flip-off cap.

The dry powder is first reconstituted with 5 mL SWFI (before further addition of SWFI) to allow space for agitation in the Sculptra vial.

A. Remove the flip-off cap from the Sculptra vial. Clean the stoppers of the Sculptra vial and SWFI vial with an antiseptic.

B. Use an 18G needle to draw 5 mL SWFI into a 5 mL syringe.

C. Use the 18G needle to add 5 mL SWFI to the Sculptra vial. Remove the syringe and needle.

D. Shake the Sculptra vial vigorously by hand for about 1 minute to dissolve the excipients. A single vial swirling agitator may be used.

E. Inspect the Sculptra vial for any remaining lumps, and if needed, shake more until a homogeneous, translucent suspension with some foam on the top is obtained.

Follow step 2 to add additional 3 mL SWFI to obtain a reconstitution volume of 8 mL (for non-facial use and optional for facial use, according to the **Treatment guide**).

2 Step FURTHER RECONSTITUTION IN THE SCULPTRA VIAL

Recommended supplies:
- Sterile Water For Injection (SWFI)
- Single-use 5 mL sterile syringe
- 18G regular wall sterile needle

A. Use an 18G needle to draw additional 3 mL SWFI (according to the **Treatment guide**) into a 5 mL syringe.

B. Add the SWFI to the vial with the reconstituted Sculptra (for a total volume of 8 mL).

C. Shake the Sculptra vial until the suspension is homogenous with some foam on the top.

3 Step ADDITION OF LIDOCAINE (OPTIONAL)

Recommended supplies:

- Antiseptic (such as alcohol)
- Sterile lidocaine hydrochloride 2% (20 mg/mL)
- Single-use 1 mL sterile syringe
- 18G regular wall sterile needle

Lidocaine solution may be added for the purpose of pain relief during the injection.

A. Clean the stopper of the lidocaine vial with an antiseptic.

B. Use an 18G needle to draw 1 mL lidocaine into a 1 mL syringe and add to the vial with the reconstituted Sculptra.

C. Shake the Sculptra vial until the suspension is homogenous.

4 Step DILUTION IN SYRINGES (FOR NON-FACIAL USE ONLY)

Recommended supplies:

- Sterile Water For Injection (SWFI)
- Single-use 10 mL sterile syringe
- Single-use 20 mL sterile syringe
- 18G regular wall sterile needle
- Single-use sterile fluid dispensing connector

A. Use an 18G needle to withdraw the suspension from the Sculptra vial into a 10 mL syringe. Tilt the vial horizontally and withdraw suspension from the lower lateral of the vial. Avoid withdrawing the foam.

B. Use an 18G needle to draw 9 mL SWFI into a 20 mL syringe.

C. Connect the 10 mL syringe and 20 mL syringes together using a fluid dispensing connector.

D. Mix the suspension by slowly pushing the suspension back and forth between syringes approximately 10 times (5 times each side).

E. Push all of the suspension into the 20 mL syringe (for a total volume of 17 mL, or 18 mL with optional lidocaine).

F. Disconnect the empty 10 mL syringe from the fluid dispensing connector.

5 Step PREPARATION OF INJECTION SYRINGES

Recommended supplies:

- Single-use 1 mL, 3 mL or 5 mL sterile injection syringes
- 18G regular wall sterile needle

A Mix the Sculptra suspension immediately before filling each injection syringe by turning the Sculptra vial or 20 mL syringe up-side down repeatedly. The particles will sediment at standing.

B Withdraw the suspension into 1 mL, 3 mL or 5 mL injection syringes. Avoid withdrawing foam from the vial.

- **For facial use**: Use an 18G needle to withdraw the suspension from the Sculptra vial into injection syringes. Tilt the vial horizontally and withdraw the suspension from the lower lateral of the vial.
- **For non-facial use** where the Sculptra suspension has been diluted in a 20 mL syringe: Use the fluid dispensing connector to connect the injection syringe to the 20 mL syringe and withdraw the suspension.

C Repeat to withdraw the remaining suspension from the Sculptra vial or 20 mL syringe into the injection syringes.

6 Step PREPARATION OF INJECTION NEEDLES OR CANNULAS

Recommended supplies:

- 25-26G thin wall sterile injection needles,
  - or -
- 22-25G blunt-end sterile injection cannulas

Use only the recommended needle/cannula sizes to reduce the risk of clogging or bending. Do not use regular wall injection needles.

When using a cannula, consult the cannula instructions for use to select an appropriate incision needle to make an entry point in the skin.

A Connect an injection needle or cannula to each injection syringe.

B Ensure that selected needle/cannula is compatible with the syringe and firmly assembled and checked for function before treatment, to avoid leakage or disconnection. The size, length, wall thickness or brand of the needle/cannula can affect the use of the product. The longer the needle/cannula is, and the smaller the inner diameter is, the higher the resistance during injection and the higher the risk of clogging, leakage or separation of the needle/cannula from the syringe.

C Expel a few drops of the suspension through the attached needle/cannula to eliminate air and check for blockage.

D Change the needle/cannula for each new treatment site to minimize the risk of infection and to avoid the use of blunt needles.

E **If clogging occurs** or the needle becomes dull

- remove the needle/cannula
- expel a small amount of the suspension
- attach a new needle/cannula
- expel a small amount of the suspension to eliminate air and check for blockage

Do not attempt to bend or manipulate the needle/cannula before or during treatment, as this could break the needle/cannula. If it is bent, discard it and complete the procedure with a replacement needle/cannula.

Do not re-use needles/cannulas.

Injection procedure

Clean the treatment site thoroughly with a suitable antiseptic solution.

Mark depressions and dimples at rest and at dynamic positions pre-treatment in the gluteal area and thighs to avoid accidently injecting into these and bending the needle during injection, or cause fat herniation or worsening of dimple appearance.

To maintain a homogeneous suspension throughout the procedure, intermittently agitate Sculptra in the vial or syringe. Do not inject foam.

Injection technique chosen should be appropriate for the intended treatment indication., e.g., antegrade or retrograde injection, linear threading, fanning, cross-hatching, serial puncture or bolus/depot techniques.

For bolus technique, 0.1 mL to 0.2 mL multiple injections are recommended, spaced 0.5 cm to 1 cm apart for facial areas and spaced 1 cm to 2 cm apart for non-facial areas.

Select the injection depth using the **Treatment guide** above.

- When using a needle,
  - Withdraw the plunger rod slightly to aspirate and verify that the needle is not in a blood vessel.
  - Inject slowly while pulling the needle backwards.
- When using a cannula,
  - Inject slowly while keeping the side hole of the cannula facing downwards away from the skin surface, to ensure that the flow of the suspension is maintained at the correct tissue depth.
- Do not apply excessive pressure to the syringe at any time. Presence of scar tissue may impede advancement of the needle/cannula. If resistance is encountered the needle/cannula should be partially withdrawn and repositioned or fully withdrawn and checked for function.
- Stop the injection immediately if the overlying skin turns a whitish color (blanching). Massage the area until it returns to a normal color. Blanching may represent vessel occlusion. If normal skin coloring does not return, do not continue with the injection.
- Stop the injection just before the needle/cannula is pulled out from the skin to prevent material from leaking out from the injection site.

Post-treatment care

- It is important to thoroughly massage the treated area(s) to evenly distribute the product (use of an appropriate cream may help to reduce the friction on the skin surface during massaging).
- If the treated area is swollen directly after injection, apply an ice pack with adequate protective cloth to the site for a short period. Use ice with caution if the area is still numb from anesthetic to avoid thermal injury.
- Monitor the patient for an appropriate time after the injection to identify potential immediate onset adverse events.
- Advise the patient on essential post-treatment care.
- Following the treatment, the patient can gently massage the treated area for a couple of minutes over the next days to promote a natural-looking correction.
- Advise the patient to contact a healthcare professional if they experience anything unusual at the treatment area.

Disposal after treatment session

- Discard the Sculptra vial, syringes, needles/cannulas, and any unused suspension immediately after the treatment session.
- Avoid re-shielding needles to prevent needle-stick injury.
- Dispose in accordance with accepted medical practice and applicable local and national requirements.
- The carton package can be recycled as paper.

Fill in on the Implant Card:

- Patient name or patient ID
- Date of treatment
- Name and address of the healthcare institution/provider

Fill in the Treatment Record

on the Implant Card or Patient Information:

- Treatment area(s)
- Injected volume per treatment area

Provide the Implant Card and Patient Information to the patient.

CE 0344

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EN 556-2, EN ISO 10993-1, EN ISO 11137-1, EN ISO 11137-2, EN ISO 13408-1, EN ISO 13408-2, EN ISO 13408-3, EN ISO 13408-4, EN ISO 13408-5, EN ISO 13408-6, EN ISO 13485, EN ISO 14155, EN ISO 14630, EN ISO 14971, EN ISO 15223-1, EN ISO 17665-1, (EU) 2022/2346.