

S SCULPTRA®

Poly-L-lactic acid

TRAINING

INSTRUCTIONS FOR USE, PATIENT INFORMATION AND TRAINING
ON ADMINISTRATION AND SAFE USE ARE AVAILABLE AT:

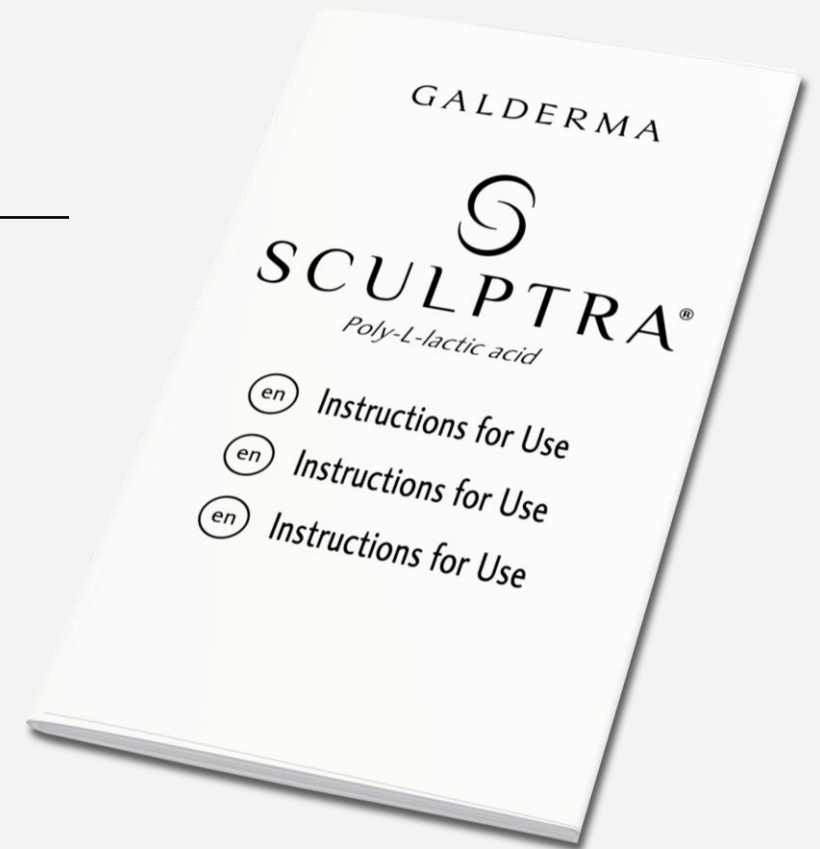
WWW.GALDERMA.COM/LIBRARY



READ THE **INSTRUCTIONS FOR USE** BEFORE USING SCULPTRA

This training may contain abbreviated and complementary information and is not intended as a replacement for the Instructions for Use.

Read the full Instructions for Use for product-specific safety information prior to using Sculptra.



MAIN MENU

- 1 Sculptra product description
- 2 Considerations before use
- 3 Warnings and Precautions
- 4 Information and documentation
- 5 Product preparation
- 6 Treatment procedure
- 7 Demonstration video



NAVIGATION

The home icon will return you to the main menu (here)



Glossary of symbols that may appear on packaging or in this training.

 Unique Device Identifier	 Single sterile barrier system with protective packaging outside	 Patient name or patient ID
 Catalogue number, for identification of the medical device	 Single sterile barrier system	 Date of treatment
 Batch code, for identification of the batch or lot	 Use-by date, indicates the date after which the medical device is not to be used	 Name and address of the healthcare institution/provider
 Manufacturer	 Upper and lower temperature limits that the product can safely be exposed to	 Consult instructions for use
 Sterilized using aseptic processing techniques	 Do not use if package is damaged	 Caution, indicates that caution is necessary or that the current situation needs operator awareness or operator action
 Do not re-use, the device is intended for one single use only		

OVERVIEW

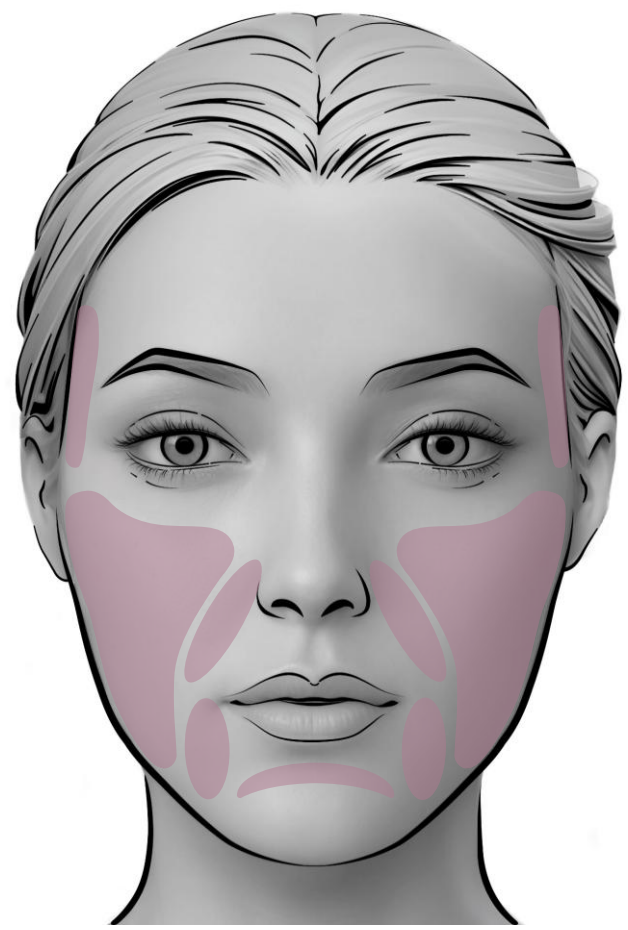
SCULPTRA PRODUCT DESCRIPTION



SCULPTRA®

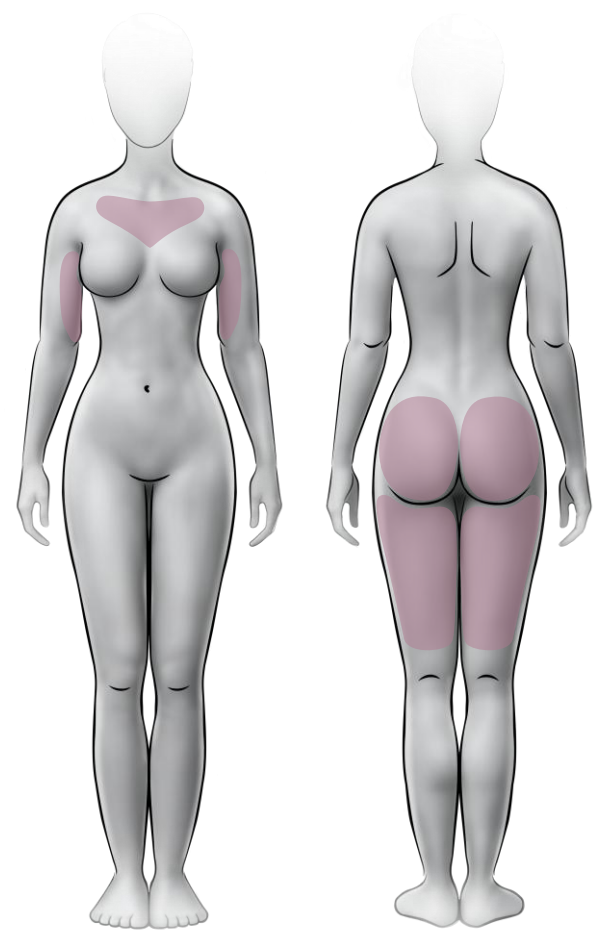
Sculptra is for aesthetic use to increase the volume of depressed areas of the face and body, particularly to correct skin creases, wrinkles, folds, cellulites, and for skin quality improvements.

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



FACIAL USE

Indicated for use in the nasolabial folds, cheeks, marionette lines, temples, chin crease

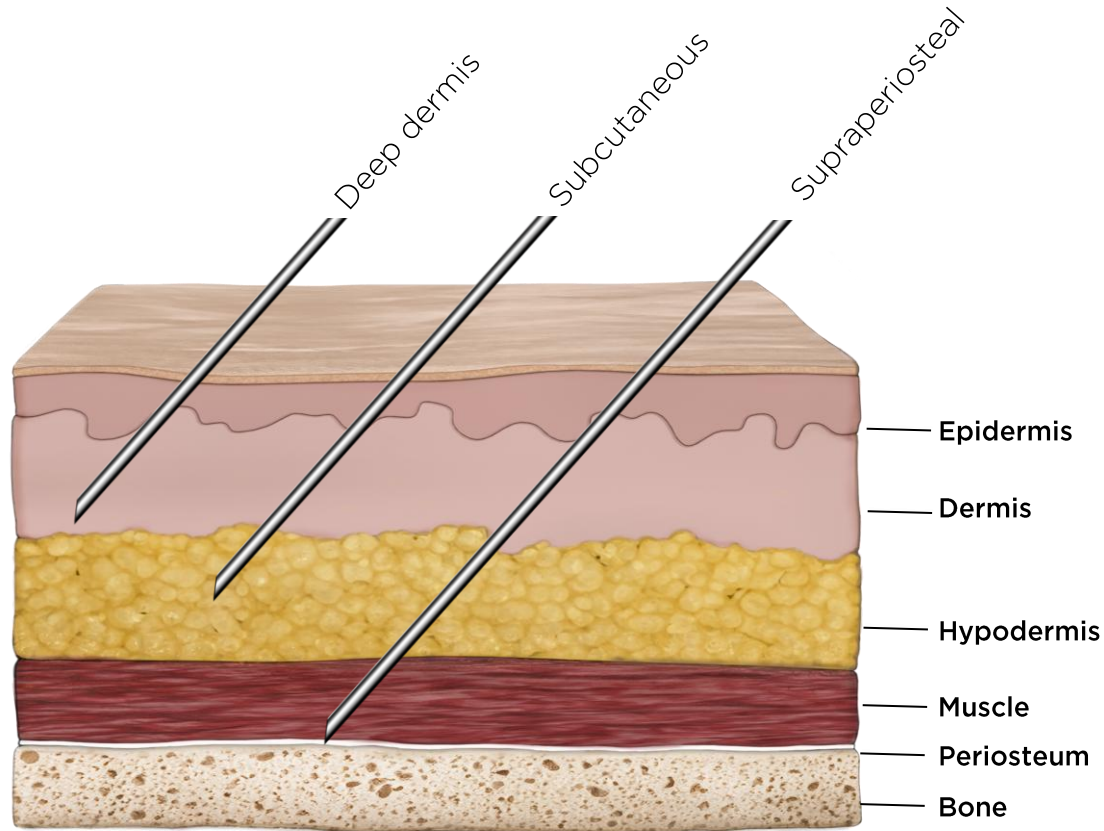


NON-FACIAL USE

Indicated for use in the décolletage, gluteal area, posterior thighs, upper arms

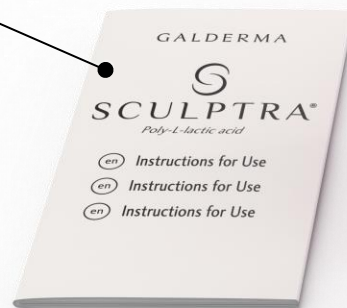
The injection depth varies for different indications.

The image shows the layers of the skin and placement of the needle for different injection depths.

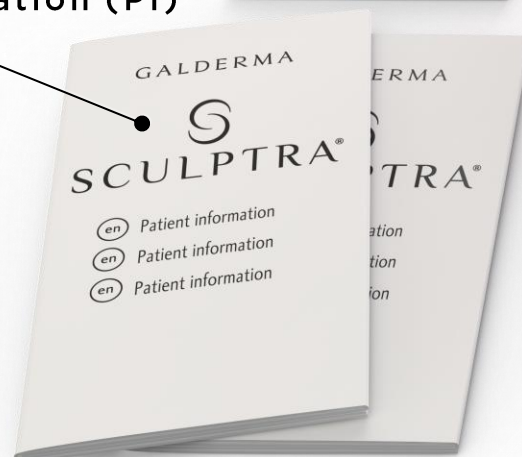


Refer to the Treatment Guide in the **Instructions for Use** to select the proper injection depth for each anatomical indication.

**Instructions for Use (IFU)
Leaflet**



**Patient Information (PI)
Leaflets**



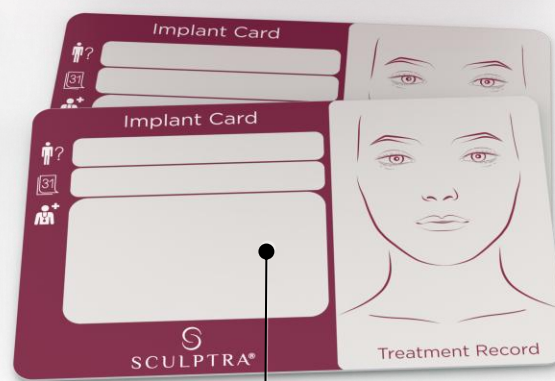
Vials
containing sterile,
dry powder



**Labels with product
information
for your records**



**Implant cards
for the patient**



CONSIDERATIONS BEFORE USE

INTENDED USERS AND PATIENT SELECTION



Sculptra should only be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.

ANATOMY

The healthcare professional should have adequate knowledge on the anatomy at the injection site to minimize the risks of complications and to achieve the desired aesthetic outcome of the treatment.

PRODUCT

The healthcare professional should ensure that they fully understand the conditions to safely and properly use the product.

TRAINING

Please contact your local Galderma representative or Sculptra distributor for more information about the preparation procedure, injection techniques, and training opportunities.



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.
- Patients with unattainable expectations are not suitable candidates for treatment.

CONTRAINDICATIONS

- Do not use in patients with a history of hypersensitivity to any constituents of the product.
- Do not use in patients with a history of anaphylaxis or history of multiple severe allergies.
- Do not add lidocaine to the suspension for patients with known hypersensitivity to lidocaine or to other amide-type local anesthetics.

PRIOR IMPLANTS

- 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.



PATIENT HISTORY

Use with caution in patients with:

- Prior surgical procedures or previous trauma in the treatment area, as this could affect the tissue and vasculature
 - Bleeding disorders or using substances that affect platelet function, thrombolytics or anticoagulants
 - Autoimmune disease or on immunosuppressive therapy
 - Pre-existing tendency toward edema formation
 - 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
 - Latent or subclinical herpes viral infections, as these may be reactivated
 - Risk factors for developing skin irritation
-
- Advise patients that inflammatory pigmentation changes and scarring might occur following soft tissue injections.

ACTIVE DISEASE

- Do not use when there is an underlying **known active systemic disease** or there is active disease (such as inflammation, injection, or tumors) in or near the treatment site, until the underlying process has been controlled.

INDIVIDUAL VARIATION

- Advise patients that individual variation and treatment area may affect the **rate of biodegradation** of the product. Product remnants might be detected in tissue even after the clinical effect has disappeared.

DIAGNOSTIC IMAGING

- Advise patients that the implanted product might appear as an **incidental finding** on subsequent diagnostic imaging with ultrasound, MRI, CT scans or standard plain radiography. Sculptra is safe in a MR (magnetic resonance) environment.

OTHER PROCEDURES

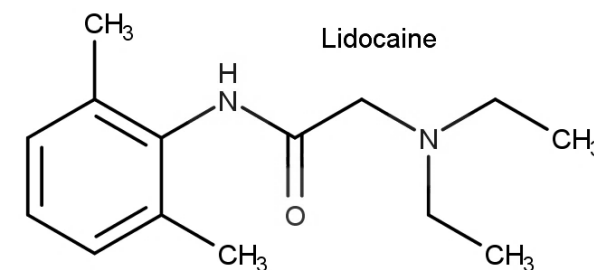
- Avoid procedures based on **active dermal response**, including laser treatment or chemical peeling, before the skin has healed completely after treatment with Sculptra. This may lead to an inflammatory reaction at the implant site.
- This also applies if Sculptra is administered before the skin has healed completely after such a procedure.

CONSULT THE INSTRUCTIONS FOR USE

for more detailed information



- **High doses of Lidocaine** (more than 4.5 mg/kg of bodyweight) can cause **acute toxic reactions** that affect the central nervous system and cardiac conduction.
- Toxicity can also occur as the result of **interaction** with similar substances. The **combined dose** of related products is relevant.
- Common substances similar to Lidocaine are amide-type local anesthetics used as **dental pain blocks** or **topical pain alleviating products**.
- **Use with caution** in patients with epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.



Dose example: Patient weight is 50 kg and a high dose of 4.5 mg/kg = 225 mg of lidocaine is used. The maximum of 6 vials per session with 1 mL of lidocaine (2% solution) added to each Sculptra vial would provide 120 mg of lidocaine. For specific safety information, refer to the product labeling for the lidocaine solution used.

Conclusion: The smaller the patient is, the more important it may be to know if lidocaine or similar substances may have been used shortly before the treatment.

WARNINGS AND PRECAUTIONS

TO MANAGE RISK OF ADVERSE EVENTS



Anatomical knowledge is a key factor in minimizing the risk of perforation or compression of vessels, nerves and other vulnerable structures.

AVOID INJECTION INTO

BLOOD VESSELS

- Do not inject intravascularly.

This can lead to embolization or occlusion of the vessels, with local ischemia and necrosis or infarction (especially in areas with limited collateral blood flow).

MUSCLES AND TENDONS

- Do not inject intramuscularly or in tendons.

This can lead to hematoma and pain in the affected area.

NERVES AND VULNERABLE AREAS

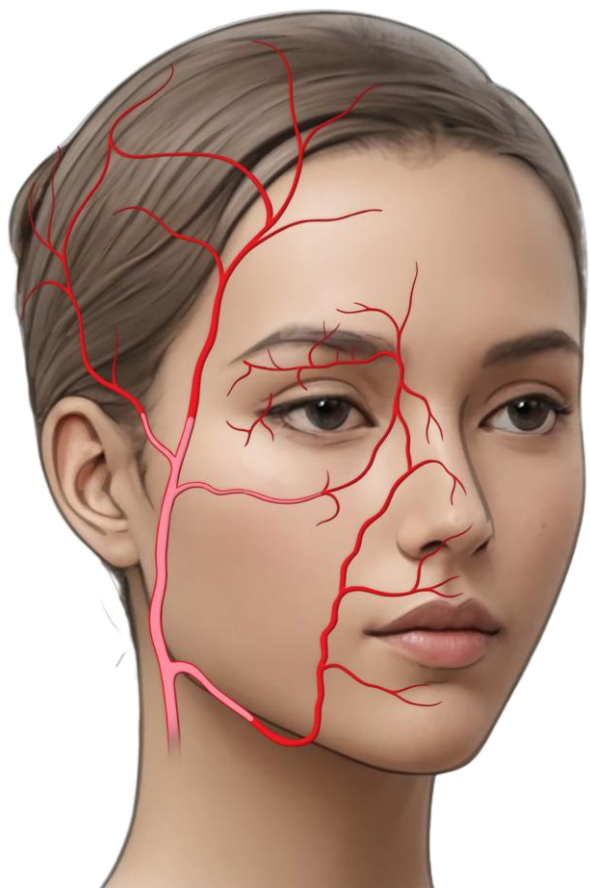
- Do not inject in nerves and other vulnerable structures, such as parotid gland.
- Do not inject into the red area of the lip (vermillion) or in the periorbital area.

This can lead to potential complications such as perforation or compression of vessels, nerves, or other vulnerable structures.



AVOIDING BLOOD VESSELS

Understanding respective patients' anatomical characteristics such as arterial branching patterns, preexisting conditions, or the similar, is important to reduce the inherent risks pertaining to inadvertent intravascular injections during treatment.



PAY EXTRA ATTENTION TO

- patients with unusual vessel anatomy
- patients with previous trauma or area(s) with altered anatomy due to a prior trauma or surgical procedure

VASCULAR OCCLUSION EVENTS CAN LEAD TO SERIOUS COMPLICATIONS

Always follow these steps to manage these risks:

1 ASSESS VISION

Perform vision assessments before and after treatment.

2 ASPIRATE

Aspiration prior to each injection is recommended.

3 INJECT SLOWLY IN SMALL VOLUMES

Inject slowly in small volumes.
Watch for signs of intravascular injection.



ASSESS VISION

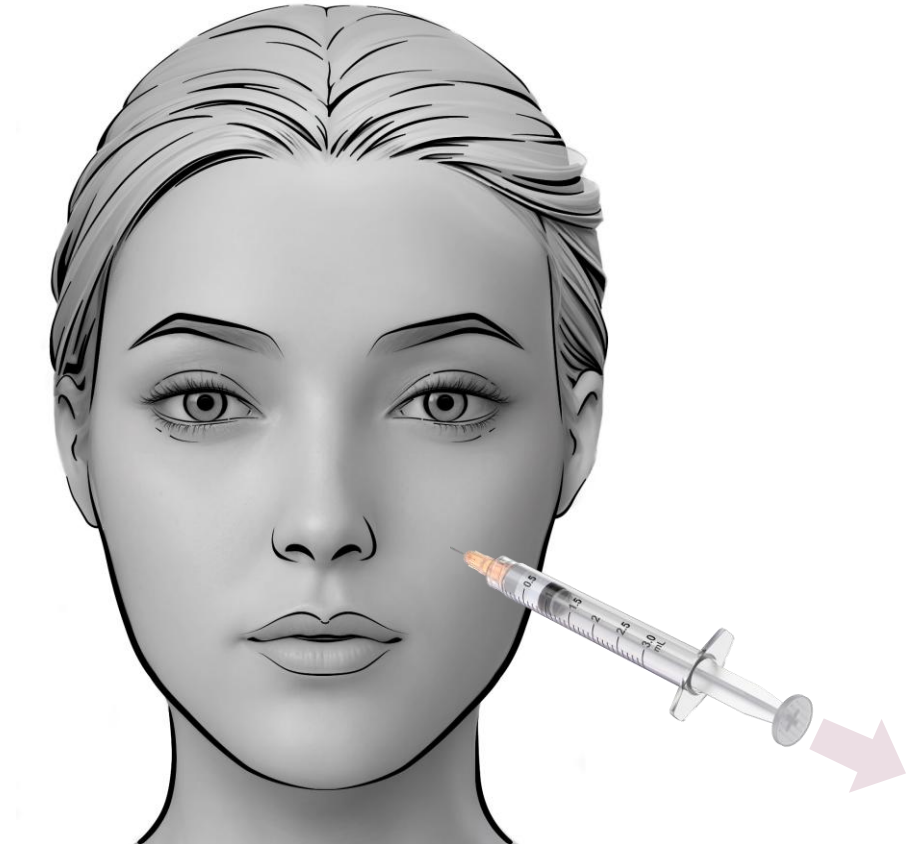
- Before and after a treatment, it is recommended to conduct a vision assessment including:
 - Visual acuity
 - Extraocular motility
 - Visual field testing
- After treatment, repeat the same vision assessments as before treatment.
- Changes in vision can indicate an intravascular event.

Identify a local ophthalmologist to be available in the event of an ophthalmic adverse event



ASPIRATE

- **Always perform aspiration prior to injection.**
- Withdraw the plunger rod slightly to aspirate and verify that no blood is visible in the syringe.
- The risk of intravascular injection can be minimized by aspiration prior to injection and slow methodical injection.



Aspiration prior to each injection is recommended for all treatment areas and injection depths.



INJECT SLOWLY IN SMALL VOLUMES

- Inject slowly and in small volumes.
- If blanching or changes in vision occur during injection, this means that a blood vessel could be blocked. **Immediately stop injecting and pull out the needle.**
- If blanching occurs, massage the area and wait for normal color to return. If normal skin color does not return, **do not continue** with the injection.

HOW AND WHEN TO ACT

Immediately stop the injection if any of the following symptoms occur:

- changes in vision,
- signs of a stroke,
- blanching of the skin, or
- unusual pain during or shortly after the procedure.

Should an intravascular injection occur, stop the injection and ensure the patient receives prompt medical attention.

Follow these steps to manage aesthetic risks such as asymmetry, deformity, papules, and nodules.

1 FOLLOW PREPARATION & INJECTION INSTRUCTIONS

- Adhere to proper product preparation and injection techniques to minimize early occurrence of papules or nodules at the injection site.

2 DO NOT OVERCORRECT

- Do not overcorrect. Over-correction may increase the risk of papules and nodules, or areas of induration.
- Use caution in areas with limited soft tissue support, thin skin (e.g., décolletage or atrophic skin).
- Avoid large bolus injections or injecting too superficially.

3 MASSAGE THE TREATMENT AREA

- Massage the treatment area to ensure proper distribution of the product to minimize the appearance of papules or nodules.

PAPULES AND NODULES RISKS

OCCURRENCE

Reported injection site papules/nodules mostly occurred several weeks up to a year post-injection; such nodules are occasionally associated with inflammation or discoloration.

Serious nodules are reported with onset 1-2 months or up to 14 months following injection and with a prolonged duration of up to 2 years in rare cases.

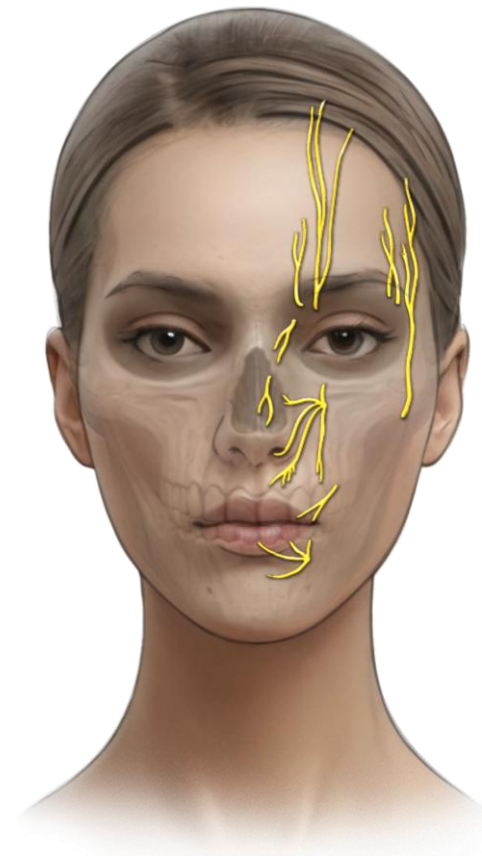
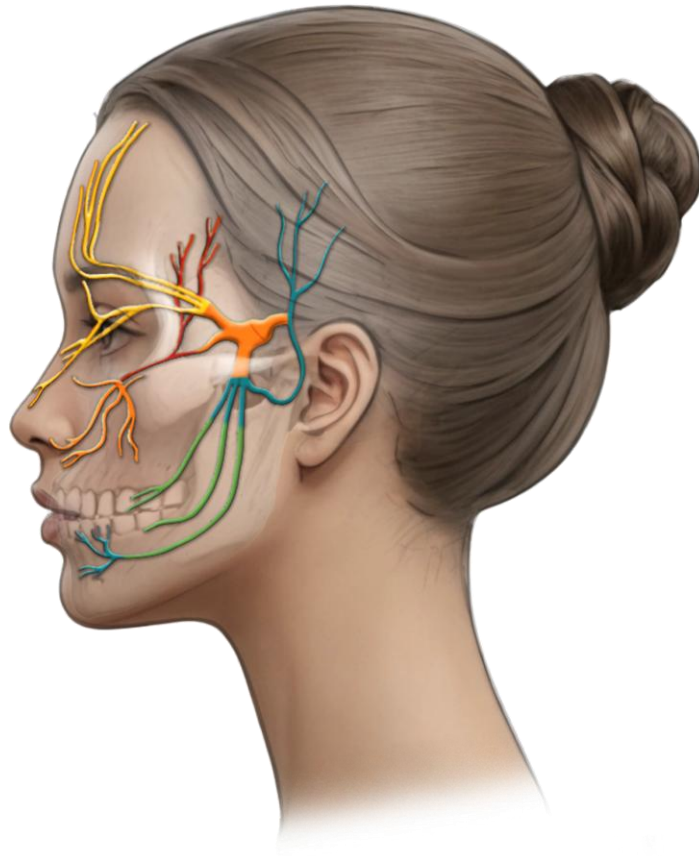
RESOLUTION

1. The papules/nodules can resolve spontaneously
2. The papules/nodules might need a treatment to resolve (e.g., intralesional corticosteroids)
3. The nodules might require surgical excision (larger nodules, nodules in difficult anatomical regions or persistent after other treatments)



AVOIDING NERVES

Do not inject in nerves and other vulnerable structures.



ANTICIPATED INJECTION RELATED REACTIONS

- Bruising/bleeding
- Pain or tenderness
- Swelling
- Erythema
- Pruritus

Injection-related reactions might occur after treatment, but typically resolve within 1 week without medical intervention.

ADVERSE EVENTS

- Adverse events captured in clinical investigations, literature, or voluntarily from post marketing surveillance can be found in the Instructions for Use.
- Reports of serious adverse events are rare.

Discuss the risk of adverse events with the patient prior to treatment. This information can also be found in the Patient Information.

INFORMATION AND DOCUMENTATION

INSTRUCTIONS FOR USE, PATIENT INFORMATION, AND IMPLANT CARDS



Inspect the label to make sure the date and lot number can be read.

Do not use the product if the expiration date has passed.



Do not use the product if the package or vial is open or damaged.

Do not mix Sculptra with other substances, other filler products, or drugs (other than lidocaine), prior to injection.

STORAGE

DRY POWDER

Store dry powder at 15-30°C

RECONSTITUTED SUSPENSION

The suspension should be used immediately after reconstitution.

The suspension may be stored in the vial (without lidocaine) for up to 72 hours at refrigeration (2-8 °C) or room temperature (up to 30 °C) at the healthcare professional's discretion (only if aseptic technique is used).

Do not freeze.

USE THE SUSPENSION IMMEDIATELY

after adding lidocaine or removing the suspension from the vial. Do not store in syringes.



Implant card

Fill in and provide to patient

Implant Card

SCULPTRA®

Treatment Record

Labels with product information

(including lot number, expiration date, unique device identifier)

Attach to your clinic's paper patient records (or record this information in your electronic patient records)



HOW TO FILL IN THE IMPLANT CARD

Patient name

Date of treatment

Name and address of healthcare institution/provider

Implant Card

Anna Andersson

27 May, 2024

Dr. Smith
AB Healthcare Center
Filler Street 7, Uppsala

SCULPTRA®

Treatment Record

2 vials,
8mL each

Treatment Record:

- Treatment area(s)
- Injected volume per treatment area
- Number of vials
- Preparation volume per vial



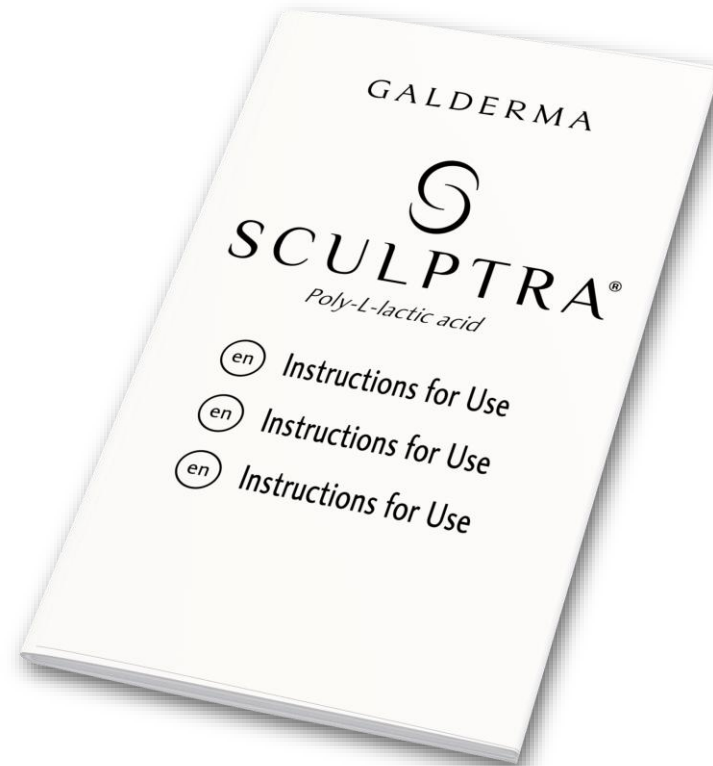
FOR THE HEALTHCARE PROFESSIONAL

The **Instructions for Use** leaflet is for Healthcare Professionals.

It includes information on:

- Indicated treatment areas
- Recommendations for injection technique, volume, and injection depth
- Needle and cannula sizes
- Adverse events
- Warnings and precautions

This information is regularly updated with **new information** from clinical use.

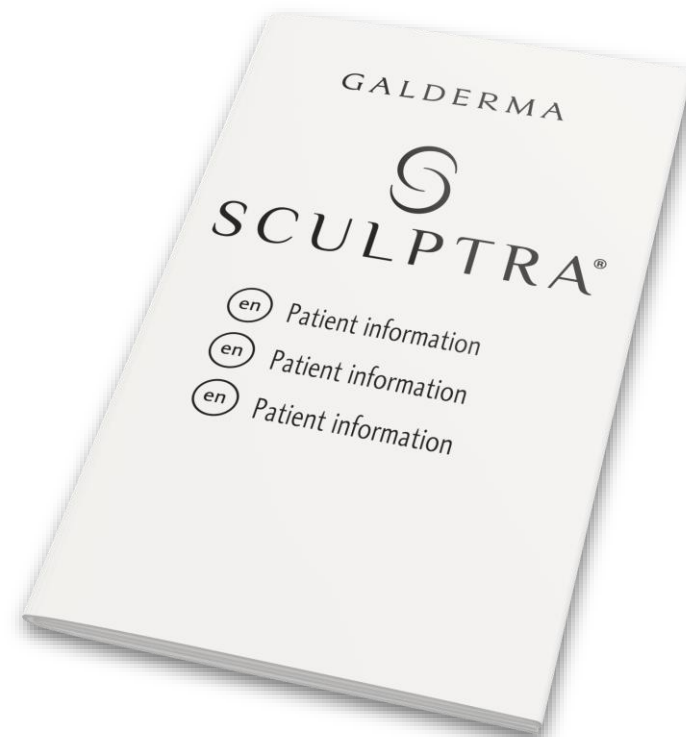


FOR THE PATIENT

The **Patient Information** leaflet is for patients.

It includes information on:

- What to expect from the treatment
- Potential side-effects
- Post-treatment instructions
- Warnings and precautions to discuss with their healthcare professional



FOR THE PATIENT

1

IMPLANT CARD

Fill in the Implant Card to provide to the patient.

Implant Card

Anna Andersson

27 May, 2024

Dr. Smith
AB Healthcare Center
Filler Street 7, Uppsala

SCULPTRA®

Treatment Record

2 vials,
8 mL each

MEDICAL DEVICE REGULATION MDR (EU) 2017/745

Medical device regulation requires an **Implant Card** and **Patient Information** be provided to the patient. Healthcare professionals should fill in and provide this information to patients.

2

PATIENT INFORMATION

Provide leaflet to the patient.

GALDERMA

SCULPTRA®

en Patient information

en Patient information

en Patient information

en Treatment Record

For the healthcare professional:
Fill in the Treatment Record.
Provide the Patient Information to the patient.

Number of vials used: 2 vials

Preparation volume
per vial: 8 ml

Treatment area(s): Nasolabial folds,
Cheeks

Injected volume per 1/2 mL per nasolabial fold
treatment area: 1/2 mL per Cheek

Treatment Record:

- Treatment area(s)
- Injected volume per treatment area
- Number of vials
- Preparation volume per vial

Note: There is additional space for completing the Treatment Record on the Patient Information leaflet.

The Treatment Record can be completed on the space provided on either the Implant Card or the Patient Information.

PRODUCT PREPARATION

SCULPTRA



TREATMENT PLANNING

Refer to the Treatment Guide to select the appropriate preparation procedure and injection depth, **depending on the anatomical indication you are planning to treat.**

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 suprapariosteal layer		Deep dermis, subcutaneous layer	Deep dermis, subcutaneous layer		

Sculptra
Select the appropriate Treatment Guide to use the suspension.

Facial use
5-9 mL per session

Reconstitution

Step 1

Step 2

Step 3

Non-Facial use
17-18 mL per session

Follow step 3 for addition of lidocaine

Step 4

Follow the Treatment Guide for preparation steps for reconstitution and dilution of the dry powder in each Sculptra vial with **sterile water for injection (SWFI)**

USE THE TREATMENT GUIDE TO SELECT:

NUMBER OF VIALS

PREPARATION VOLUMES
(FOR EACH VIAL)

INJECTION DEPTH

NUMBER OF SCULPTRA VIALS

Do not exceed the number of Sculptra vials identified in the Treatment Guide.
Follow the preparation procedures to prepare each Sculptra vial with the selected volume.

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.

Treatment guide

Sculptra Preparation Steps	Anatomical indication					
	Facial use		Non-facial use			
	Face	Lipoatrophy	Décolletage	Upper arm	Gluteal area	Posterior thigh
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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 suprapariosteal layer		Deep dermis, subcutaneous layer	Deep dermis, subcutaneous layer		

Sculptra

Select the appropriate Treatment Guide to use the suspension.

Facial

5-9 mL per session

Reconstitution

Step 1

Step 2

Step 3

Non-Facial

17-18 mL per session

Follow step 3 for additional

Step 4

Do not exceed the maximum number of vials identified for each anatomical indication.

Do not exceed in any single treatment session a total of:

6 VIALS



GENERAL USE CONDITIONS

Use aseptic technique throughout the preparation procedure.



- Prepare and inject the product in a clinical environment, such as a medical office.
- Start with a clean work space and wear medical gloves.
- Work under aseptic and hygienic conditions.
- Use only sterile, single-use supplies.

OVERVIEW OF PREPARATION PROCEDURES

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The Treatment Guide includes different preparation procedures for:

FACIAL USE

5-9 mL per Sculptra vial



RECONSTITUTION IN THE SCULPTRA VIAL

- 1 Reconstitution in the Sculptra vial **+ 5 mL** SWFI
- 2 Further reconstitution in the Sculptra vial **+ 3 mL** SWFI
(*optional for facial use*)
- 3 Addition of lidocaine **+ 1 mL** lidocaine
(*optional*)

NON-FACIAL USE

17-18 mL per Sculptra vial



RECONSTITUTION IN THE SCULPTRA VIAL

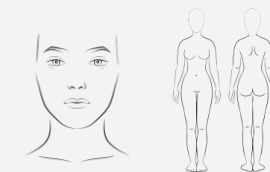
- 1 Reconstitution in the Sculptra vial **+ 5 mL** SWFI
- 2 Further reconstitution in the Sculptra vial **+ 3 mL** SWFI
- 3 Addition of lidocaine **+ 1 mL** lidocaine
(*optional*)

ADDITIONAL DILUTION IN SYRINGES

- 4 Dilution in syringes **+ 9 mL** SWFI



Start by reconstituting the dry powder in the Sculptra vial for all preparations (facial and non-facial use).



CLEAN VIAL WITH ANTISEPTIC

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



ADD 5 ML SWFI TO SCULPTRA VIAL

- Use an 18G regular wall needle to add 5 mL SWFI to the Sculptra vial.

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



SHAKE VIGOROUSLY

- Shake the Sculptra vial vigorously for about 1 minute.



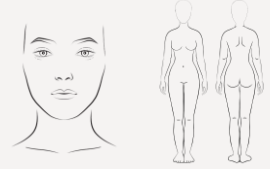
INSPECT FOR LUMPS

- Inspect the vial for any remaining lumps of dry powder.
- If needed, shake more until a homogenous, translucent suspension with some foam on the top is obtained.



2 FURTHER RECONSTITUTION IN THE SCULPTRA VIAL

Add an additional 3 mL of sterile water to the vial.



ADD 3 ML SWFI TO SCULPTRA VIAL

- Use an 18G regular wall needle to add an additional 3 mL SWFI to the vial with the reconstituted Sculptra.



SHAKE VIGOROUSLY

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

This step should always be performed for **non-facial use** but is optional for facial use.

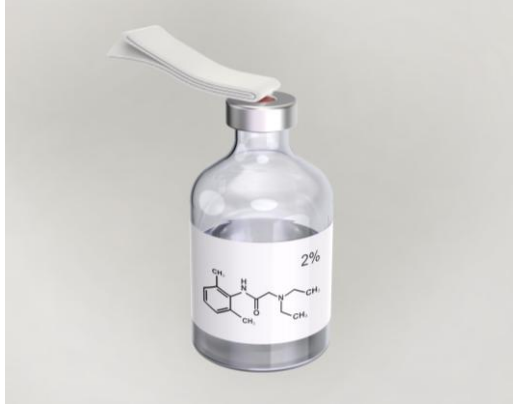
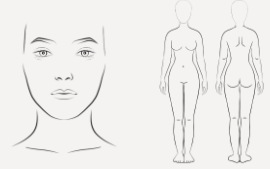
Refer to the **Treatment Guide** to select the appropriate preparation volume for the planned treatment.



3 ADDITION OF LIDOCAINE (OPTIONAL)

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Lidocaine hydrochloride 2% solution may be added for the purpose of pain relief during the injection.



CLEAN VIAL WITH ANTISEPTIC

- Clean the stopper of the lidocaine vial.



ADD 1 ML LIDOCAINE

- Use an 18G regular wall needle to add 1 mL of 2% lidocaine solution.



SHAKE VIGOROUSLY

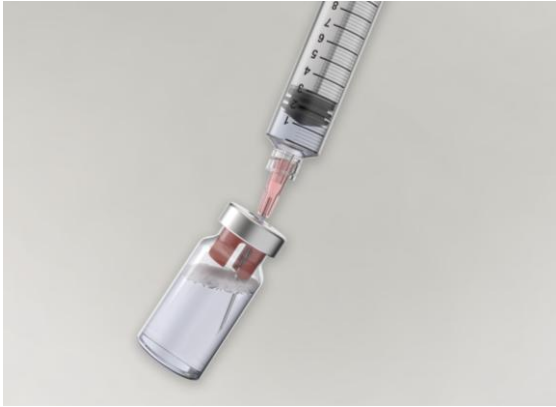
- Shake the Sculptra vial until the suspension is homogenous.



4 DILUTION IN SYRINGES (NON-FACIAL USE ONLY)

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For non-facial use, the suspension is further diluted in syringes (outside of the Sculptra vial).



DRAW SUSPENSION INTO 10 ML SYRINGE

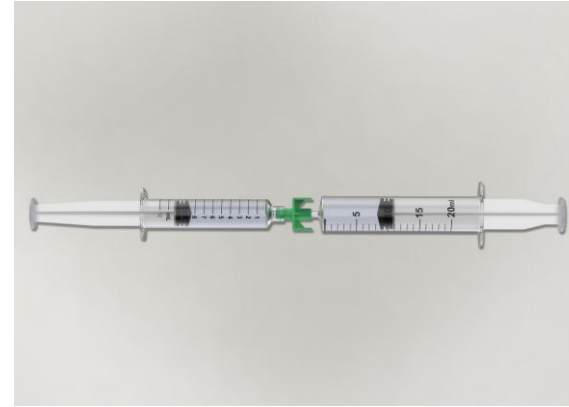
- Use an 18G regular wall needle to withdraw the suspension from the Sculptra vial into a 10 mL syringe.

Tilt the vial and withdraw from the bottom of the vial to **avoid withdrawing foam**.



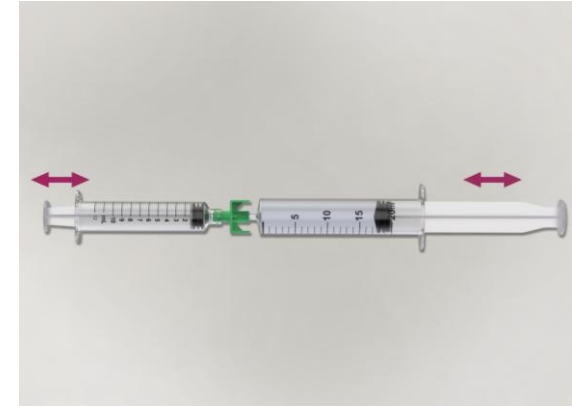
DRAW 9 ML SWFI INTO A 20 ML SYRINGE

- Draw 9 mL SWFI into a separate 20 mL syringe.



CONNECT THE TWO SYRINGES

- Connect the 10 mL syringe and the 20 mL syringe together using a syringe connector.



MIX BETWEEN SYRINGES

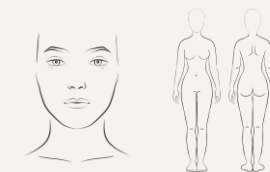
- Mix the suspension by slowly pushing the suspension back and forth between syringes.
- After mixing, push all of the suspension into the 20 mL syringe.



5 PREPARATION OF INJECTION SYRINGES

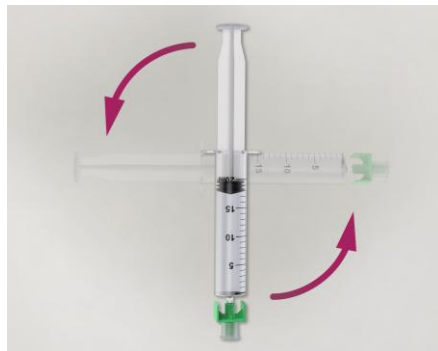
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The prepared suspension is filled into 1 mL, 3 mL, or 5 mL injection syringes.



MIX THE SUSPENSION

- Mix the Sculptra suspension immediately before filling each injection syringe.
- Turn the Sculptra vial or 20 mL syringe up-side down repeatedly.



FILL INJECTION SYRINGES

If you prepared the suspension in the Sculptra vial for **facial use**:

- Use an 18G regular wall needle to withdraw the suspension from the Sculptra vial into an injection syringe.

Tilt the vial and withdraw from the bottom of the vial to **avoid withdrawing foam**.



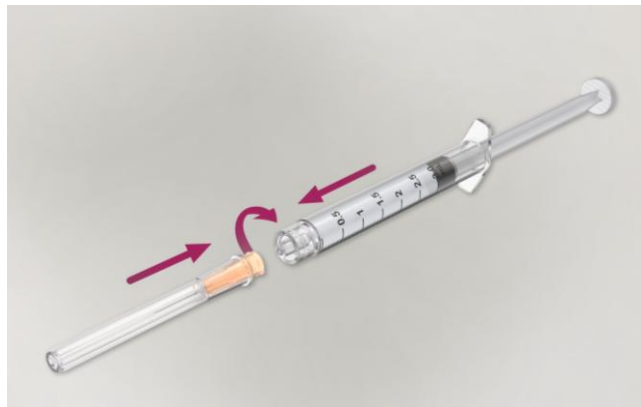
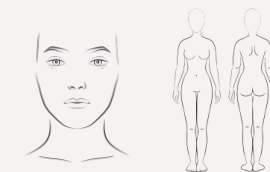
If you diluted the suspension in a 20 mL syringe for **non-facial use**:

- Use the syringe connector to connect an injection syringe to the 20 mL syringe and withdraw the suspension.



6 INJECTION NEEDLES/CANNULAS

Injection needles or cannulas are connected to each injection syringe.



CONNECT INJECTION NEEDLE/CANNULA

- Connect an injection needle or cannula to each injection syringe.
- Ensure the needle/cannula is firmly assembled and checked for function before treatment.



PRIME THE NEEDLE/CANNULA

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

Use only recommended needle/cannula sizes to reduce the risk of clogging or bending:

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

Do not use regular wall injection needles.

Check for function prior to treatment, to avoid leakage or disconnection. The longer the needle/cannula is, and the smaller the inner diameter is, the higher the resistance while injecting.

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

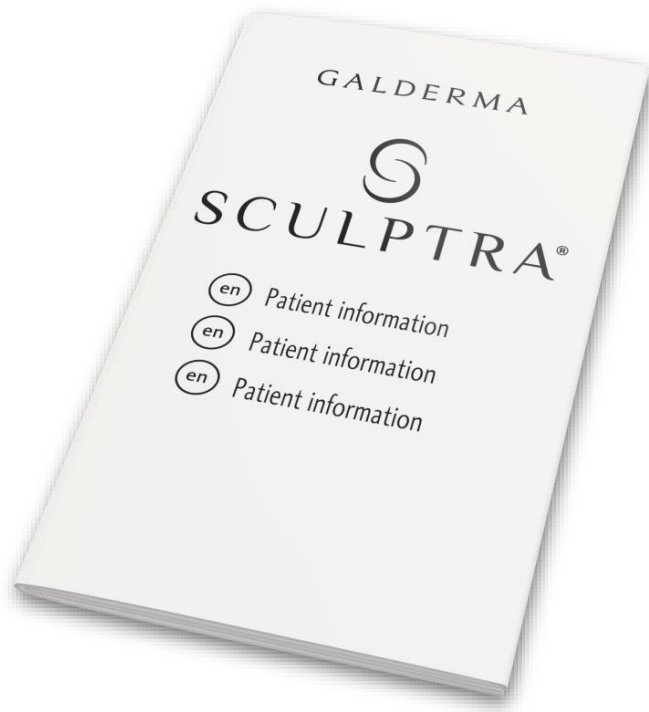


TREATMENT PROCEDURE

PERFORMING AN INJECTION AND POST TREATMENT CARE



PRIOR TO TREATMENT



- Obtain a thorough medical history as part of the patient selection process.
- Provide the patient with a copy of the Patient Information for review.
- Inform the patient about:
 - Indications and contraindications
 - Warnings and precautions
 - Expectations on treatment outcome
 - Potential adverse events
 - Essential post-treatment care
- It is recommended to conduct pre-treatment vision assessments (visual acuity, extraocular motility, visual field testing).
- Assess the patient's need for additional pain relief.

TREATMENT PLANNING

1 FIRST TREATMENT SESSION

4 weeks

2 FOLLOW-UP SESSION

4 weeks

3 FOLLOW-UP SESSION

4 weeks

4 FOLLOW-UP SESSION

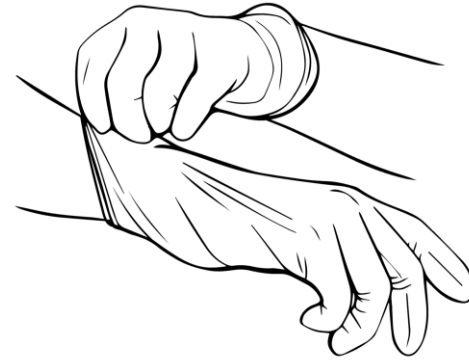
- Inform the patient that the amount of Sculptra and the number of injection sessions will depend on the patient's need and the severity of the depressed area.
- The treatment effects of Sculptra appear gradually over a few weeks.
- Perform only a limited correction during the first injection session.
- A treatment cycle of 4 treatment sessions, spaced at least 4 weeks apart is generally recommended.

GENERAL USE CONDITIONS

- Only use this product in an appropriate clinical setting.
- **Use aseptic technique** and follow standard practice to prevent cross-infections.
- Wear medical gloves.
- **Clean the treatment site** thoroughly with a suitable antiseptic solution.

NEEDLES AND CANNULAS

- **Do not attempt to bend or manipulate** the needle or cannula before or during treatment as this can break the needle/cannula.
- **Discard and replace** a needle or cannula which is damaged in any way, before the procedure is continued.

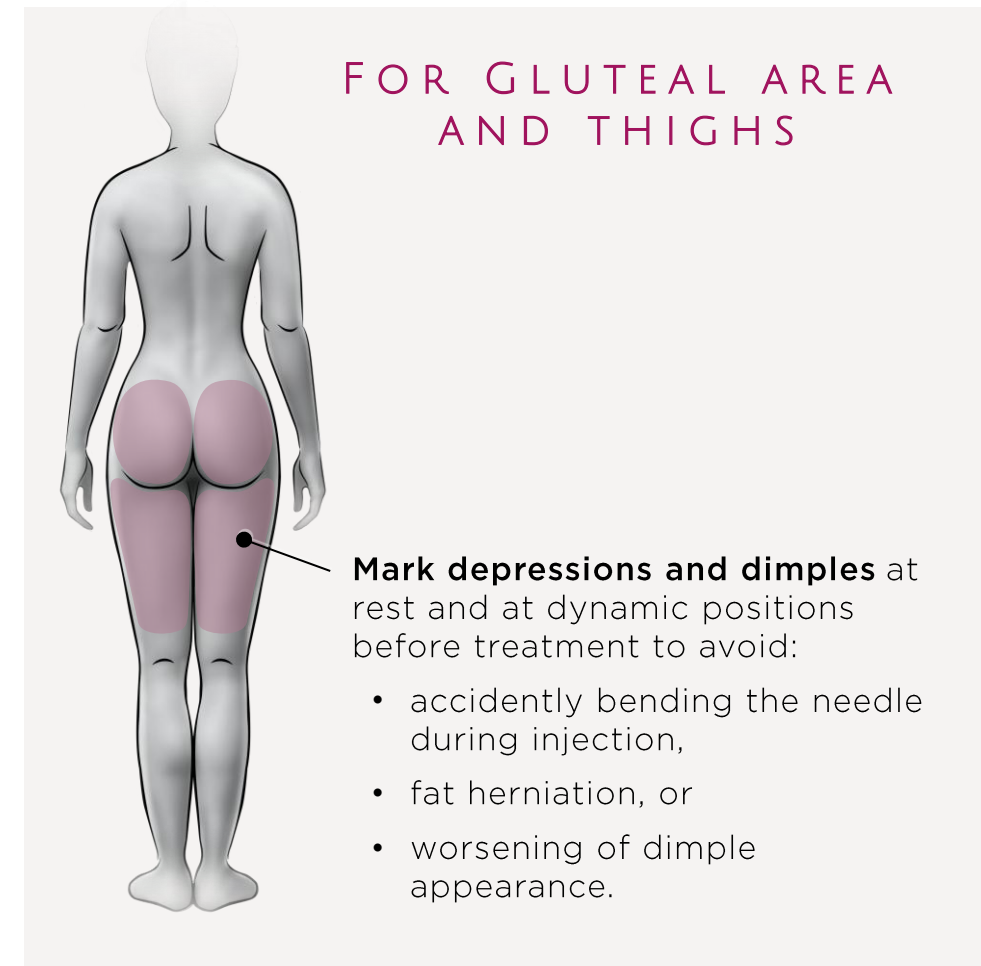


SCULPTRA SUSPENSION

- To maintain a homogenous suspension, **intermittently agitate** the Sculptra suspension throughout the procedure. Do not inject foam.
- **Use the suspension immediately** after addition of lidocaine or removal from the Sculptra vial. Do not store the suspension in syringes.

INJECTION TECHNIQUES

- **Choose an appropriate injection technique** for the intended treatment indication (e.g., antegrade or retrograde injection, linear threading, fanning, cross-hatching, serial puncture or bolus/depot techniques).
- **For bolus techniques:**
 - Recommended injection volumes:
 - 0.1 mL to 0.2 mL injections
 - Distance between injections:
 - facial areas: 0.5-1 cm apart
 - non-facial areas: 1-2 cm apart
- **Refer to the Instructions for Use for more detailed information**



PROCEDURE

1 ASPIRATE

At each new injection site, withdraw the plunger rod slightly and verify that no blood is visible in the syringe.

2 PERFORM THE INJECTION

When using a needle, inject slowly while pulling the needle backwards.

When using a cannula, inject slowly while keeping the hole of the cannula facing away from the skin surface. Use an incision needle of appropriate size to make an entry point in the skin at each new injection site.

3 STOP THE INJECTION

just before the needle/cannula is pulled out of the skin to prevent product from leaking out from the injection site.

4 CHANGE THE NEEDLE/CANNULA

for each new treatment site minimize the risk of infection and to avoid the use of blunt needles.

5 MESSAGE TREATED AREAS

immediately after the injection procedure to evenly distribute the product.

INJECT SLOWLY WITH EVEN PRESSURE

- Inject applying even pressure on the plunger rod.
- **Do not apply excessive pressure to the syringe at any time.**
- On resistance, reposition or fully withdraw the needle/cannula and check for function.
- If clogging occurs, remove the needle/cannula. Expel a small amount of suspension.
- Replace the needle/cannula, if needed.



APPLY AN ICE PACK

If the treated area is swollen directly after the injection, apply an ice pack to the site for a short period. Be careful if the area is still numb from anesthetic to avoid cold injury.

MONITOR THE PATIENT

Monitor the patient for an appropriate time after the injection to identify potential immediate onset adverse events.

AVOID UNTIL THE SKIN HAS HEALED**EXCESSIVE SUN / TEMPERATURES**

Avoid excessive sun, UV lamp exposure and extreme temperatures until any initial swelling and redness has resolved.

DERMAL TREATMENTS

Do not perform laser-based treatments, chemical peeling or any other procedures based on active dermal response until the skin is completely healed after the injection.

Skin treatments such as these may cause an inflammatory reaction in the recently treated site.



INFORM THE PATIENT

1 WHEN TO CONTACT A HEALTHCARE PROFESSIONAL

Inform the patient about the need to contact a healthcare professional if experiencing anything unusual in the treated areas.

2 POST TREATMENT CARE

Advise the patient on essential post-treatment care.

Tell the patient to **gently massage** the treated area for a couple of minutes over the next few days to ensure proper product distribution and aesthetic outcome.

3 PATIENT INFORMATION

Fill in the Implant Card.

Fill in the Treatment Record (on the Implant Card or Patient Information).

Provide the Implant Card and Patient Information to the patient.



DISPOSAL

SINGLE USE ONLY

Do not re-sterilize or reuse the product. This may lead to an infection.
The product is for single patient and single session use only.

BIOHAZARD RISK

Handle used needles and syringes as biohazards.
Avoid re-shielding used needles to prevent needle-stick injury.



DISPOSE OF SYRINGE AND NEEDLE

Discard leftover material immediately after use.

Dispose of the Sculptra vial, syringes, and any unused suspension in accordance with accepted medical practice and applicable local requirements.



Dispose of vials, syringes, and needles/cannulas in sharps containers.

DEMONSTRATION VIDEO

SCULPTRA



The following video provides a review of important information described in this training.
Read the full Instructions for Use for additional safety information prior to using Sculptra.

DEMONSTRATION VIDEO

[CLICK TO WATCH](#)



THANK YOU

FOR COMPLETING THIS TRAINING

If you have any questions about how to safely use the products, please contact your local Galderma representative or Sculptra distributor.

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

