GALDERMA

SCULPTRA®

ACTIVATE SKIN POWER

Naturally rebuild skin's own collagen, for long-lasting results

HCP BROCHURE
FOR FACE & BODY

מאושר FDA

*The first PLLA launched in the market.
**The only collagen biostimulator with primary indication in IFU for face and body usages in some regions.

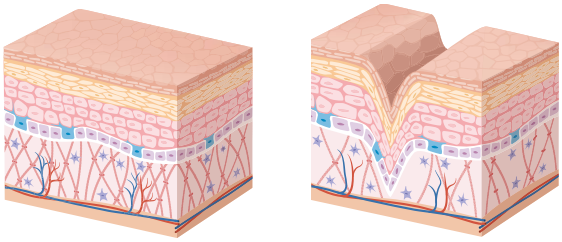
AMI technologies

COLLAGEN, THE SECRET BEHIND A FIRM AND YOUTHFUL SKIN

COLLAGEN IS A KEY COMPONENT FOR HEALTHY AND YOUTHFUL SKIN.

It is one of the most abundant proteins in the body which helps in maintaining skin's shape and firmness.[1,2]

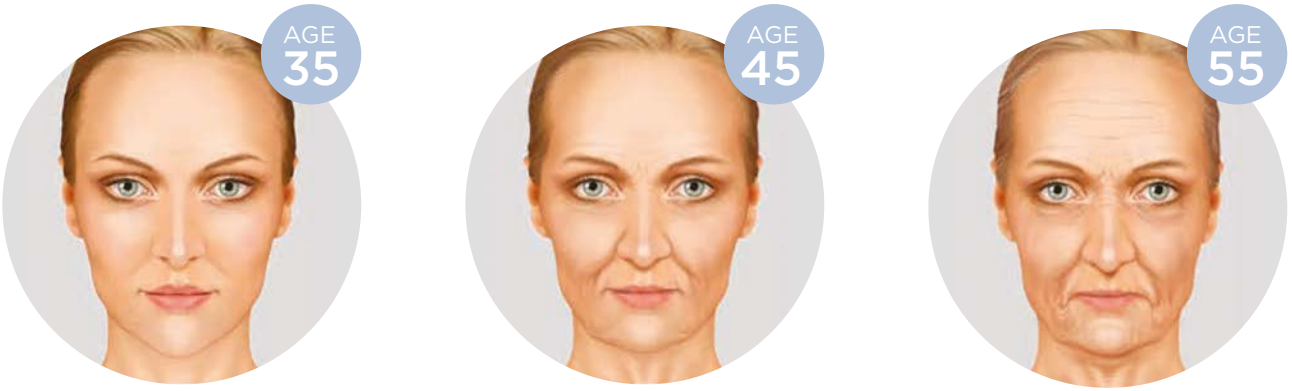
BY THE AGE OF 45, UP TO 25% OF COLLAGEN IS LOST.[3]



18 years 45 years

As we age, skin will wrinkle and sag as a result of the accelerated and progressive loss and fragmentation of collagen fibres.[4-6]

In the aging face, the development of wrinkles and furrows reflects the dynamic, cumulative effects of time on the skin, soft tissues, and deep structural components of the face.[7]



RESTORE OVERALL SKIN SHAPE AND FIRMNESS WITH BIOSTIMULATORS

THE VISIBLE SIGNS OF FACIAL AGING ARE LINKED TO THE CUTANEOUS AGING CHANGES SEEN THROUGHOUT THE REST OF THE BODY.[8]

Although the aging changes in the face are often the most apparent ...[9]

... the body areas are affected as well.[8]

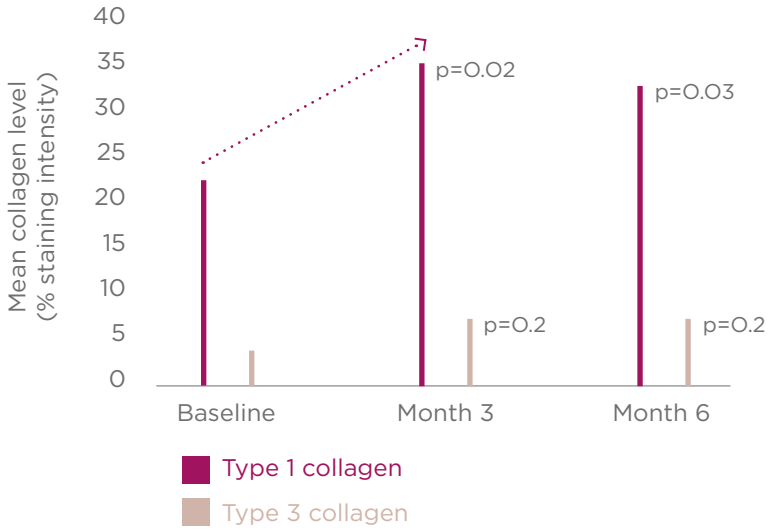
Factors such as weight loss and post-pregnancy may favour the loss of skin elasticity and increase skin sagging.[10]

Biostimulators, such as poly-L-lactic acid (PLLA), may be used not only for facial rejuvenation but also for the treatment of non-facial areas to correct skin laxity and for body contouring.[11]

SCULPTRA®: MORE THAN JUST ANOTHER FILLER

SCULPTRA® ADDRESSES THE UNDERLYING CAUSE OF FACIAL AGING AND STIMULATES THE PRODUCTION OF TYPE 1 COLLAGEN.*[12,13]

+66.5% increase in type 1 collagen after 3 months



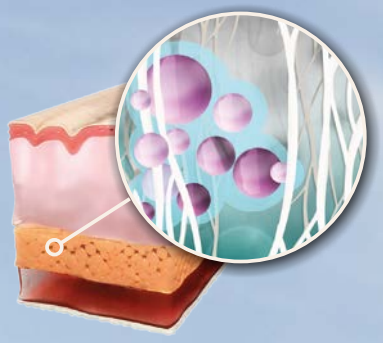
Adapted from Goldberg D, et al. 2013[13]

BY STIMULATING THE PRODUCTION OF COLLAGEN TYPE 1, SCULPTRA® CAN RESTORE SKIN FIRMNESS, QUALITY AND RADIANCE.[13,14,17]

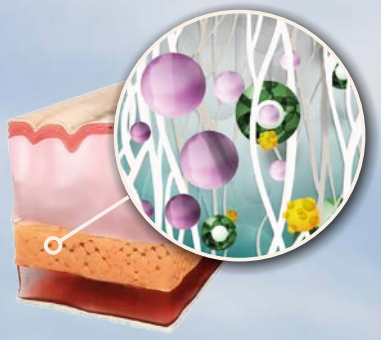
*The increase in the levels of type 3 collagen did not reach statistical significance.[13]

SCULPTRA®'S EFFECTS BEGIN DEEP UNDER THE SKIN

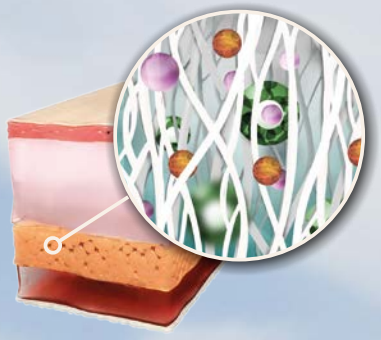
Sculptra® is the *original* and *unique* injectable collagen biostimulator containing microparticles of PLLA. [13,18]



PLLA microparticles are injected into the deep dermis



PLLA particles recruit fibroblasts



The fibroblasts deposit collagen which helps in reinforcing the skin's inner structure

PLLA works deep within the skin to stimulate the natural replacement of lost collagen.* [13,19]

SCULPTRA®

TRIPLE ACTION FOR THE FACE & BODY

Improves skin structure and quality [14-16]

Improves skin firmness [15,17]

Restores skin support by increasing the thickness of the dermis [19]

*Skin biopsies demonstrate that this formation of new collagen is accompanied only by a mild, controlled tissue response.[15]

SCULPTRA® IS THE KEY TO FIRMER AND REJUVENATED AREAS

SCULPTRA® GRADUALLY REBUILDS THE SKIN'S STRUCTURAL FOUNDATION[14,19]

Improved skin elasticity and overall skin quality and radiance following the increase in collagen levels[14]

12 MONTHS AFTER LAST TREATMENT*

SKIN ELASTICITY†

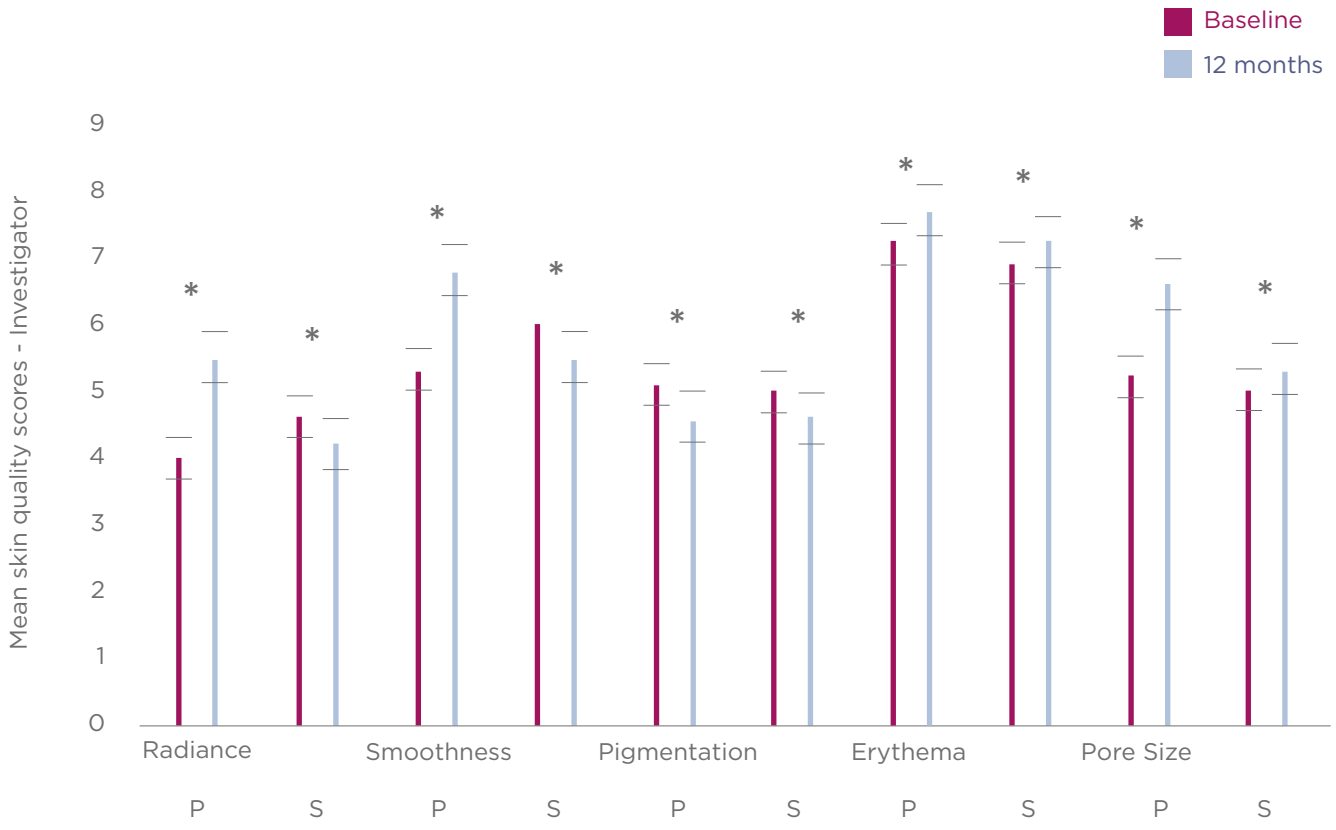
SKIN RADIANCE‡

SKIN SMOOTHNESS‡

*Randomised, controlled, double-blind, multicentre study. Patients received 3 treatments every 4 weeks with either PLLA (treatment group) or saline (control group) injections.[14] †Increase in skin elasticity at 12 months in the PLLA-treated group vs control (p = 0.0017). The increase was also associated with time (p = 0.0004).[14] ‡Global skin quality improvement included radiance, smoothness, and pigment uniformity as well as a decrease of erythema index and pore size.[14]

SCULPTRA® TREATMENTS REJUVENATE AND IMPROVE SKIN QUALITY

GLOBAL EFFECT OF REPEATED INJECTIONS OF PLLA ON SKIN QUALITY† AFTER 12 MONTHS[14]



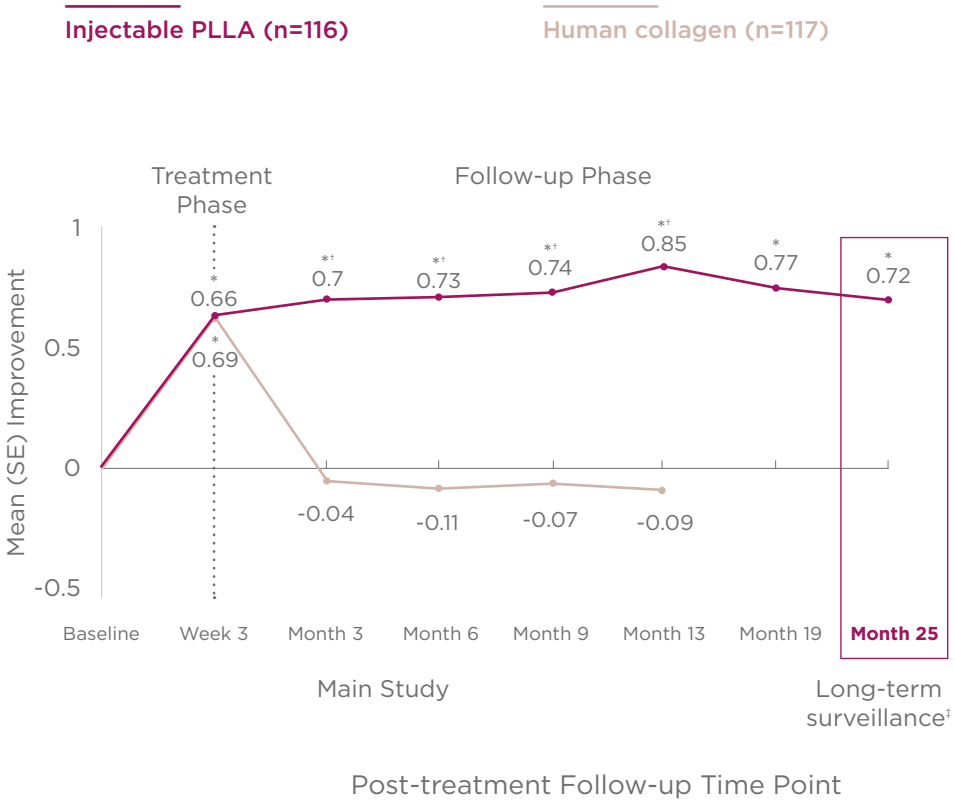
P=poly-L-lactic acid treatment S=saline treatment *=statistical significance

Adapted from Bohnert K, et al. 2019[14]

†Global skin quality improvement included radiance, smoothness, and pigment uniformity as well as a decrease of erythema index and pore size.[14]

SCULPTRA®: PROVEN EFFICACY FOR MORE THAN 2 YEARS

GRADUAL, NATURAL-LOOKING RESULTS THAT LAST[20,21]



Adapted from Narins RS, et al. 2010[20]

IMPROVEMENT IN THE APPEARANCE OF WRINKLES UP TO AT LEAST 25 MONTHS AFTER LAST TREATMENT[20,21]

*p<0.001 vs baseline.
†p<0.001 vs human collagen
‡Only subjects treated with Sculptra® (n = 106) were included in long-term surveillance phase.

SCULPTRA®
INJECTION AREAS FACE

SCULPTRA® INJECTION AREAS*[22]

Sculptra® should be injected into the deep dermis (areas marked in green)

SCULPTRA® INJECTION AREAS TO AVOID*[22]

Sculptra® should not be used in these areas as the dermis is thin (areas marked in red)

SUPPORT LOSS[23]

Injection technique: *bolus*
Device: needle 24G – 26G ½
Injection depth: supraperiosteal
Volume: 0.1 mL – 0.3 mL per point

FAT LOSS[23]

Injection technique: fan technique (entry through preauricular angle or mandibular angle)
Device: cannula 23G – 25G
Injection depth: subcutaneous
Volume: 0.2 mL per cm^2

SKIN LAXITY[23]

Injection technique: retroinjection
Device: needle 24G – 26G
Injection depth: subdermical
Volume: 0.02 mL per retroinjection

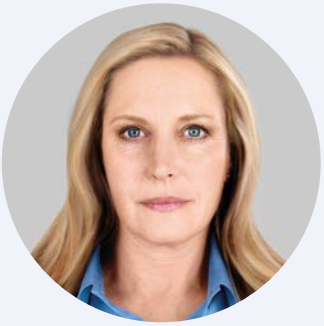
*Common injection and procedure-related side effects usually resolve spontaneously within 2 to 7 days and include injection site pain, localised swelling, tenderness, redness, itching, and bruising.[20,24]

SCULPTRA® INCREASES SKIN FIRMNESS AND DELAYS THE NORMAL COURSE OF SAGGING IN THE AGING FACE.

ELISSA, 49

Before

45 days after 2nd sessions



25 months after treatment

Actual patient. Individual results may vary.
Treated with 5 vials of Sculptra®, 3 sessions.

CARA, 42

Before

8 months after treatment

Actual patient. Individual results may vary.
Treated with 3 vials of Sculptra®, 3 sessions.

STEWART, 54

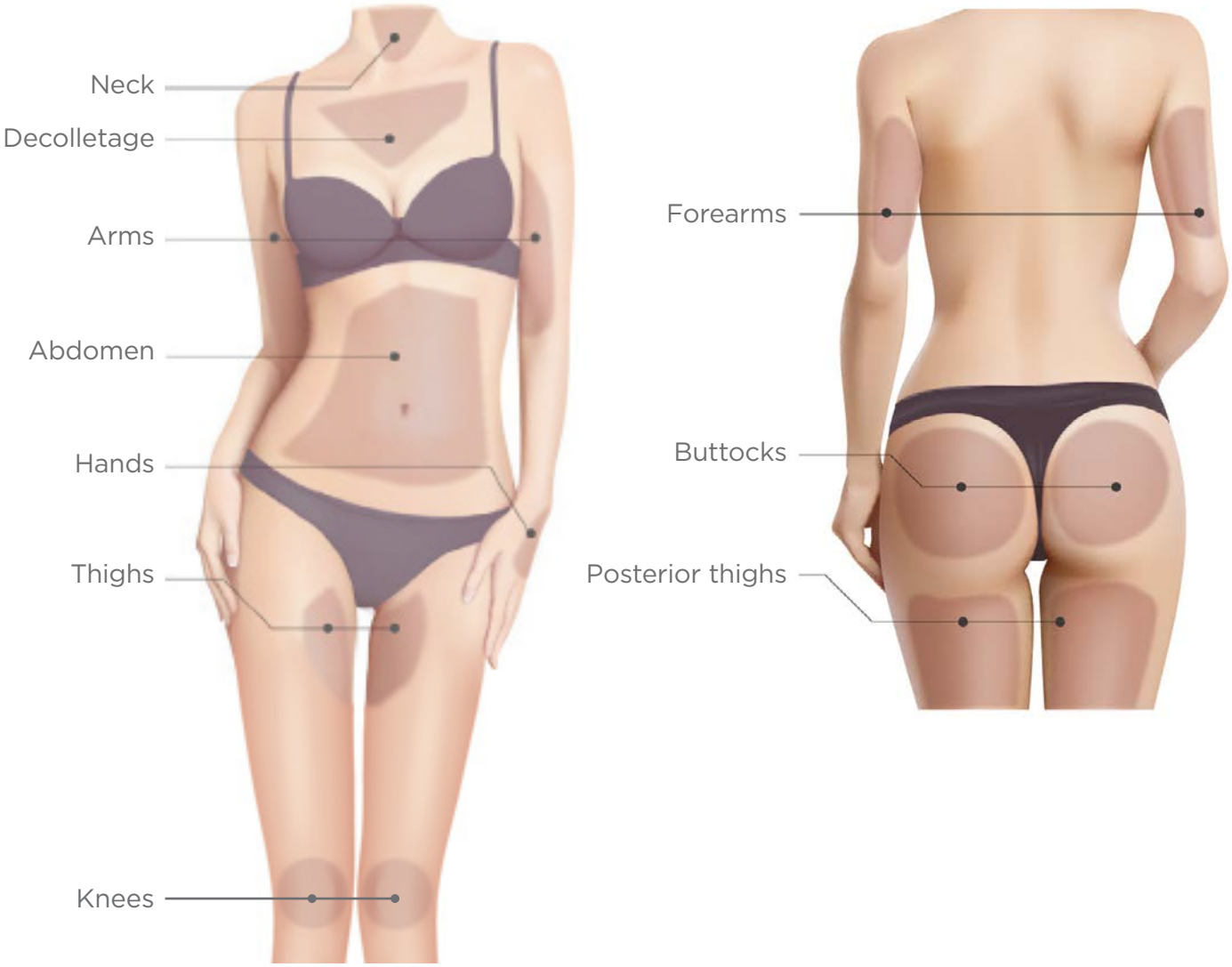
Before

7 months after treatment

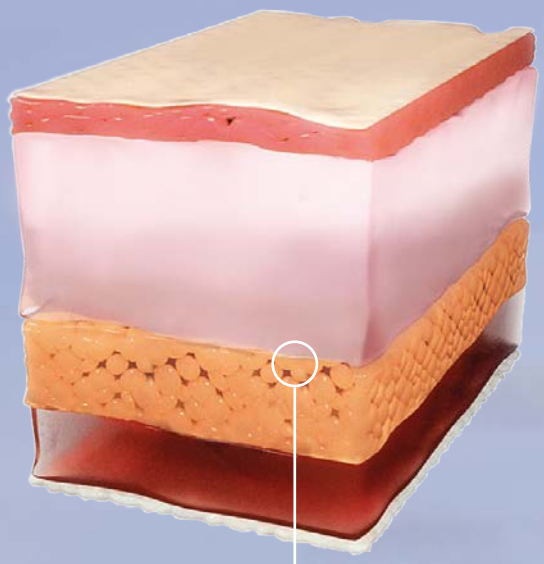
Actual patient. Individual results may vary.
Treated with 5 vials of Sculptra®, 3 sessions.

SCULPTRA®
POTENTIAL NON-FACIAL INJECTION AREAS*

Sculptra® has a safety and efficacy profile extensively evaluated in nearly 30 studies for body usage.[10,19,25-51]



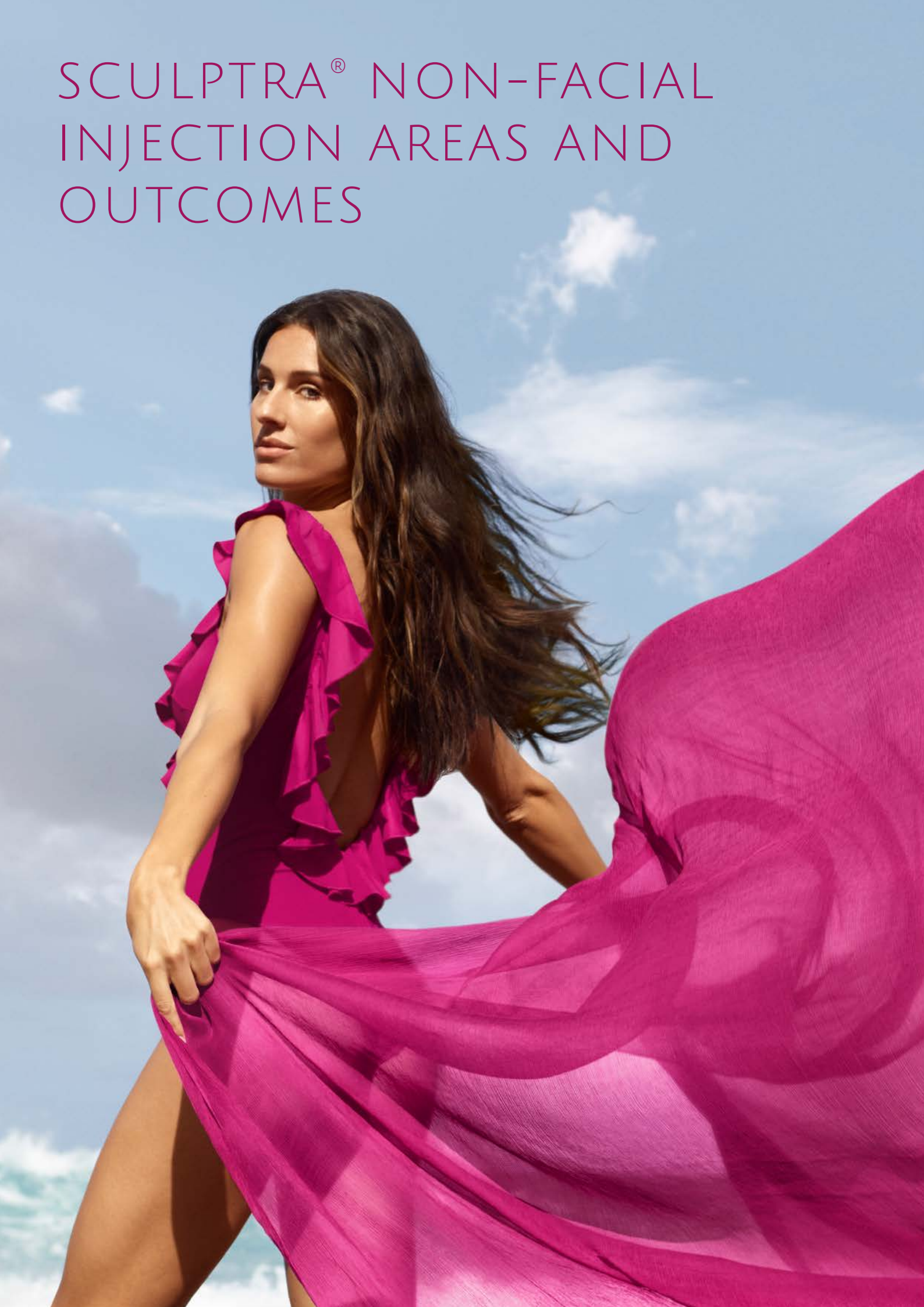
SCULPTRA® INJECTION DEPTH FOR NON-FACIAL AREAS



Superficial subcutaneous tissue.

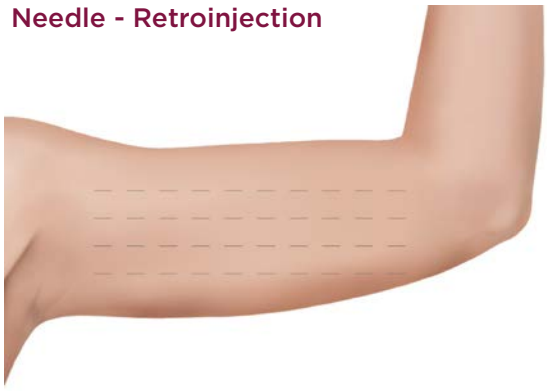
The correct injection depth for non-facial treatment with Sculptra® is the superficial subcutaneous tissue.[52]

SCULPTRA® NON-FACIAL INJECTION AREAS AND OUTCOMES

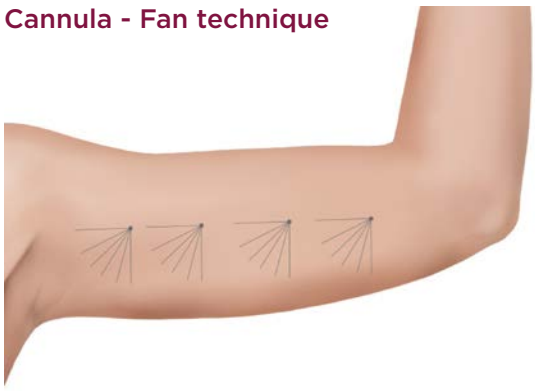


ARMS[19]

Needle - Retroinjection



Cannula - Fan technique



Volume: 0.05 – 0.1 mL per cm^2

IMPROVEMENT IN THE APPEARANCE OF SKIN LAXITY IN THE ARMS[19]

Before

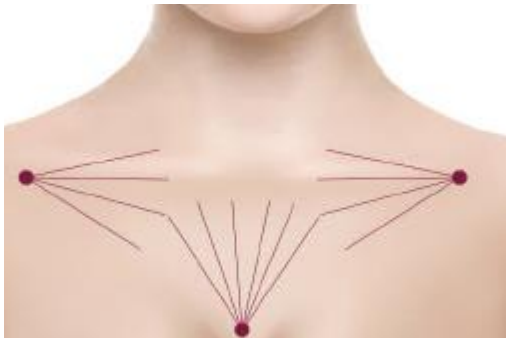
3 months after

ARMS OF A 72-YEAR-OLD WOMAN

Actual patient. Individual results may vary.

Treated with 2 monthly sessions of Sculptra® (1 vial per session).

DECOLLETAGE



ABDOMEN[19]

Needle - Retroinjection

Cannula - Fan technique

Volume: 0.05 – 0.1 mL per cm^2

REDUCTION OF SAGGING SKIN IN THE ABDOMEN[19]

Before

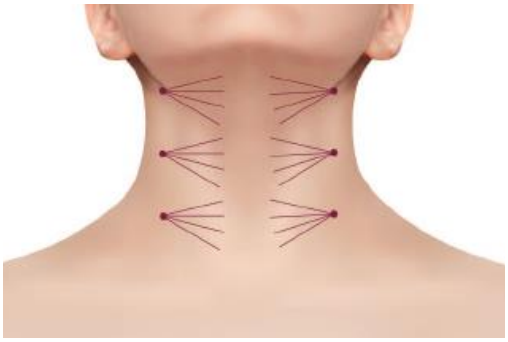
45 days after

ABDOMEN OF A 43-YEAR-OLD WOMAN

Actual patient. Individual results may vary.

Treated with 1 vial of Sculptra®.

NECK



BUTTOCKS[19]

Needle - Retroinjection

Cannula - Fan technique

Volume: 0.05 – 0.1 mL per cm^2

REDUCTION OF SAGGING SKIN IN THE BUTTOCKS[19]

BUTTOCKS OF A 34-YEAR-OLD WOMAN

Actual patient. Individual results may vary.

Treated with 3 monthly sessions (1 vial per session) of Sculptra®

SCULPTRA®: HIGH PATIENT SATISFACTION FOR MORE THAN 2 YEARS

*81% of patients rated their results as «improved» to «excellent improvement» at 25 months.[52] †86% of patients continued to show IGE scores of improvement up to 25 months after the last treatment.[20]

Follow the recommended reconstitution protocol

Ensure that the environment is sterile

Inject at the appropriate depth

Inject the appropriate volume

Massage the area immediately after the treatment

RECONSTITUTION PROTOCOL FOR **FACIAL AREAS***

The recommended two-step reconstitution protocol for immediate Sculptra® use:†

1. Add 5 mL sterile water for injection and shake vigorously for about 1 minute, until homogeneous suspension is achieved.
2. Add additional 3 mL of sterile water for injection and shake again until suspension is homogeneous.
3. To make the injection more comfortable, add 2 mL of 2% lidocaine to the solution immediately before injecting.
4. Prepare 4 syringes of 2.5 mL (2 per side)
5. Use cannula 22*70 or 22*50 or 25g needle

THE INCIDENCE OF NODULES IS BELOW 1% WHEN USING THE CORRECT RECONSTITUTION METHOD AND INJECTION TECHNIQUE.[16]

*Common injection and procedure-related side effects usually resolve spontaneously within 2 to 7 days and include injection site pain, localised swelling, tenderness, redness, itching, and bruising.[7,17]
†Global indication (except Brazil and US).
‡Adding 5 mL first, followed by 3 mL, provides extra space within the vial in the first stage for vigorous shaking.

RECONSTITUTION PROTOCOL FOR **NON-FACIAL AREAS***

The recommended two-step reconstitution protocol for immediate Sculptra® use:†

1. Add 5 mL sterile water for injection and shake vigorously for about 1 minute, until homogeneous suspension is achieved.
2. Add additional 3 mL of sterile water for injection and shake again until suspension is homogeneous.
3. Aspirate the solution to syringe of 20 mL. Add 10 mL of sterile water for injection.
4. To make the injection more comfortable, add 2 mL of 2% lidocaine to the solution immediately before injecting.
5. Solution 1: Prepare 4 syringes of 5 mL syringe
   Solution 2: Prepare 8 syringes of 2.5 mL syringe
6. Use cannula of 22*70 or 22*50

SCULPTRA® REBUILDS THE SKIN'S STRUCTURAL FOUNDATION

NOT ANOTHER FILLER

The *original* and *unique* injectable collagen biostimulator containing microparticles of biocompatible PLLA.[13,18]

THE KEY TO FIRMER AND REJUVENATED SKIN

Increases skin firmness and delays the normal course of sagging in the aging face.[15,17]

Increases skin elasticity and improves overall skin quality and radiance following the increase in collagen levels 12 months after last treatment.[14]

PROVEN EFFICACY FOR MORE THAN 2 YEARS

Gradual and long-lasting results: improvement in the appearance of wrinkles up to at least 25 months after last treatment.[20,21,53]

HIGH PATIENT SATISFACTION FOR MORE THAN 2 YEARS

In more than 8 out of 10 patients.[53]

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ABBREVIATIONS:
G = Gauge system; **IGE** = Investigator Global Evaluations; **PLLA** = Poly-L-lactic acid.

GALDERMA

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This material is exclusive to Brazil, which is allowed to promote Sculptra® for body indication.