

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.

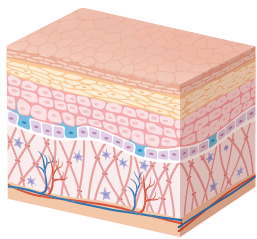


COLLAGEN, THE SECRET BEHIND A FIRM AND YOUTHFUL SKIN

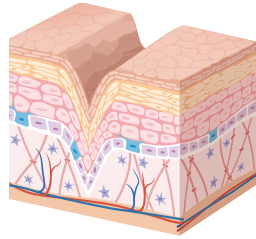
COLLAGEN IS A KEY COMPONENT FOR HEALTHY AND YOUTHFUL SKIN.

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



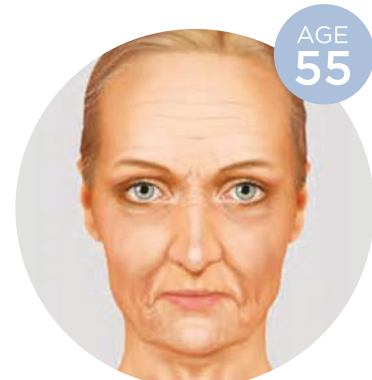
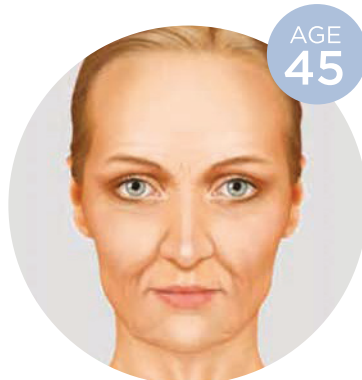
18 years



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

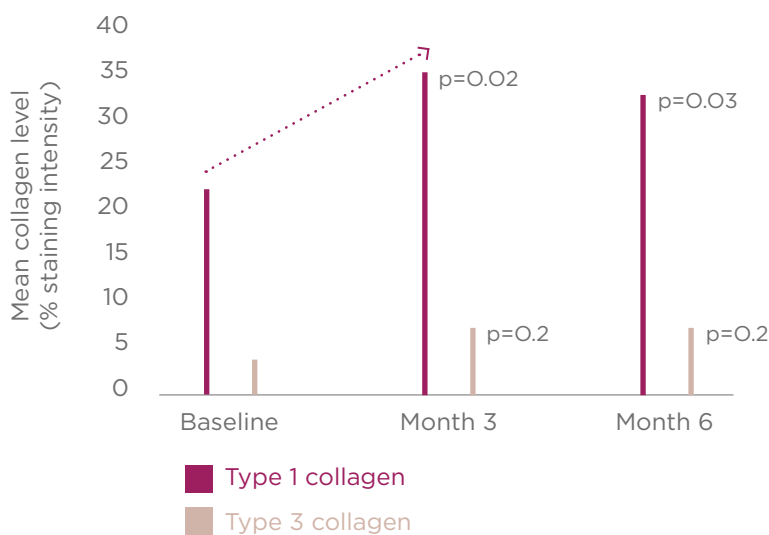
Biostimulators, such as poly-L-lactic acid (PLLA), may be used not only for facial rejuvenation but also for the treatment of non-facial areas to correct skin laxity and for body contouring.¹¹



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. 2013¹³

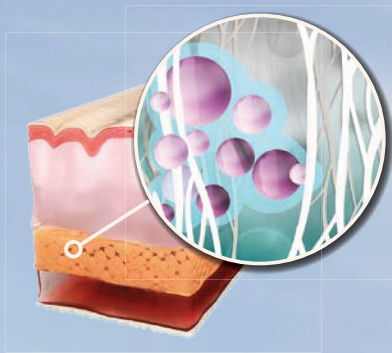
BY STIMULATING THE PRODUCTION OF COLLAGEN TYPE 1, SCULPTRA® CAN RESTORE SKIN FIRMNESS, QUALITY AND RADIANCE.^{13,14,17}

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

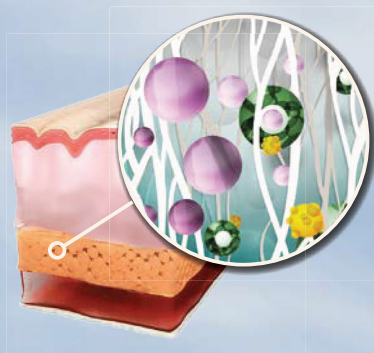


SCULPTRA®'S EFFECTS BEGIN DEEP UNDER THE SKIN

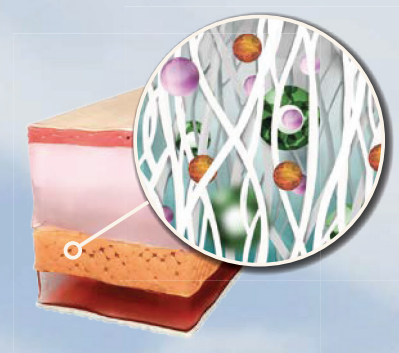
Sculptra® is the *original and unique* injectable collagen biostimulator containing microparticles of PLLA.^{13,18}



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



*Skin biopsies demonstrate that this formation of new collagen is accompanied only by a mild, controlled tissue response.¹³

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 levels¹⁴

12 MONTHS AFTER LAST TREATMENT*

SKIN
ELASTICITY[†]



SKIN
RADIANCE[‡]



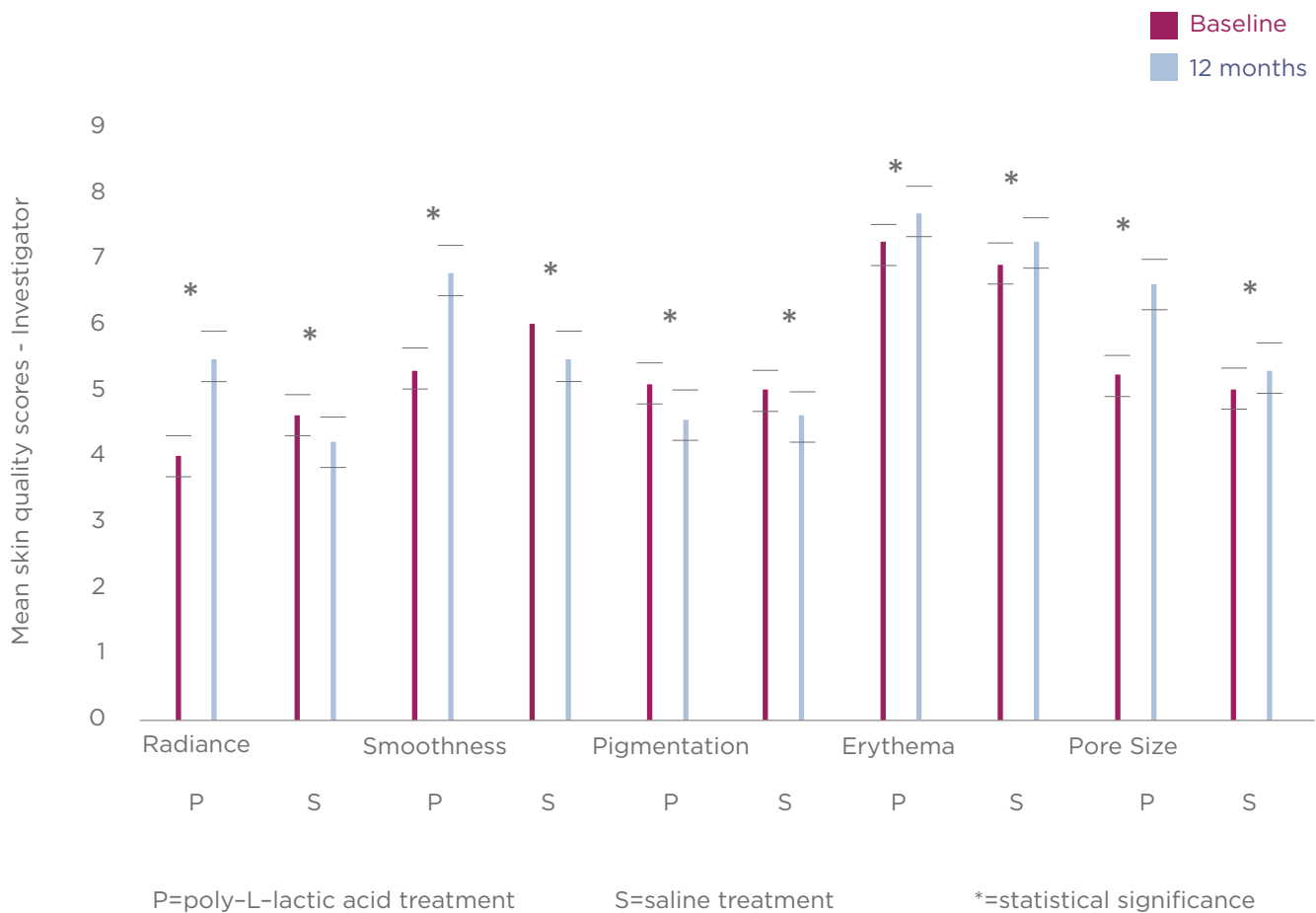
SKIN
SMOOTHNESS[‡]



*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 MONTHS¹⁴



Adapted from Bohnert K, et al. 2019¹⁴

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

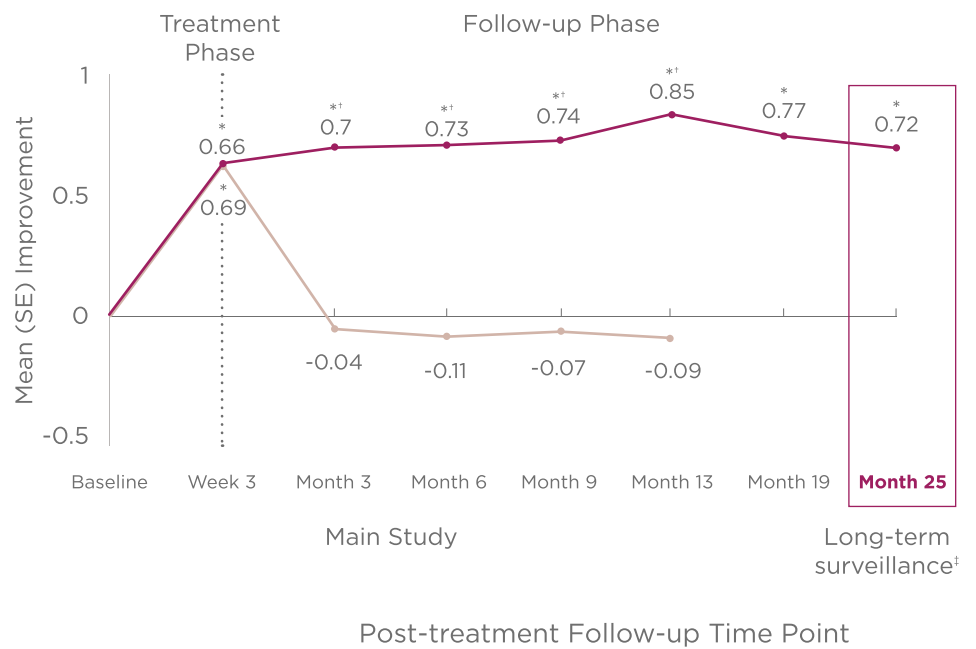
SCULPTRA®: PROVEN
EFFICACY FOR MORE
THAN 2 YEARS



GRADUAL, NATURAL-LOOKING RESULTS THAT LAST^{20,21}

Injectable PLLA (n=116)

Human collagen (n=117)



Adapted from Narins RS, et al. 2010²⁰

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 LOSS²³

Injection technique: *bolus*

Device: needle 24G - 26G ½

Injection depth: supraperiosteal

Volume: 0.1 mL - 0.3 mL per point



FAT LOSS²³

Injection technique: fan technique (entry through preauricular angle or mandibular angle)

Device: cannula 23G - 25G

Injection depth: subcutaneous

Volume: 0.2 mL per cm²



SKIN LAXITY²³

Injection technique: retroinjection

Device: needle 24G - 26G

Injection depth: subdermal

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

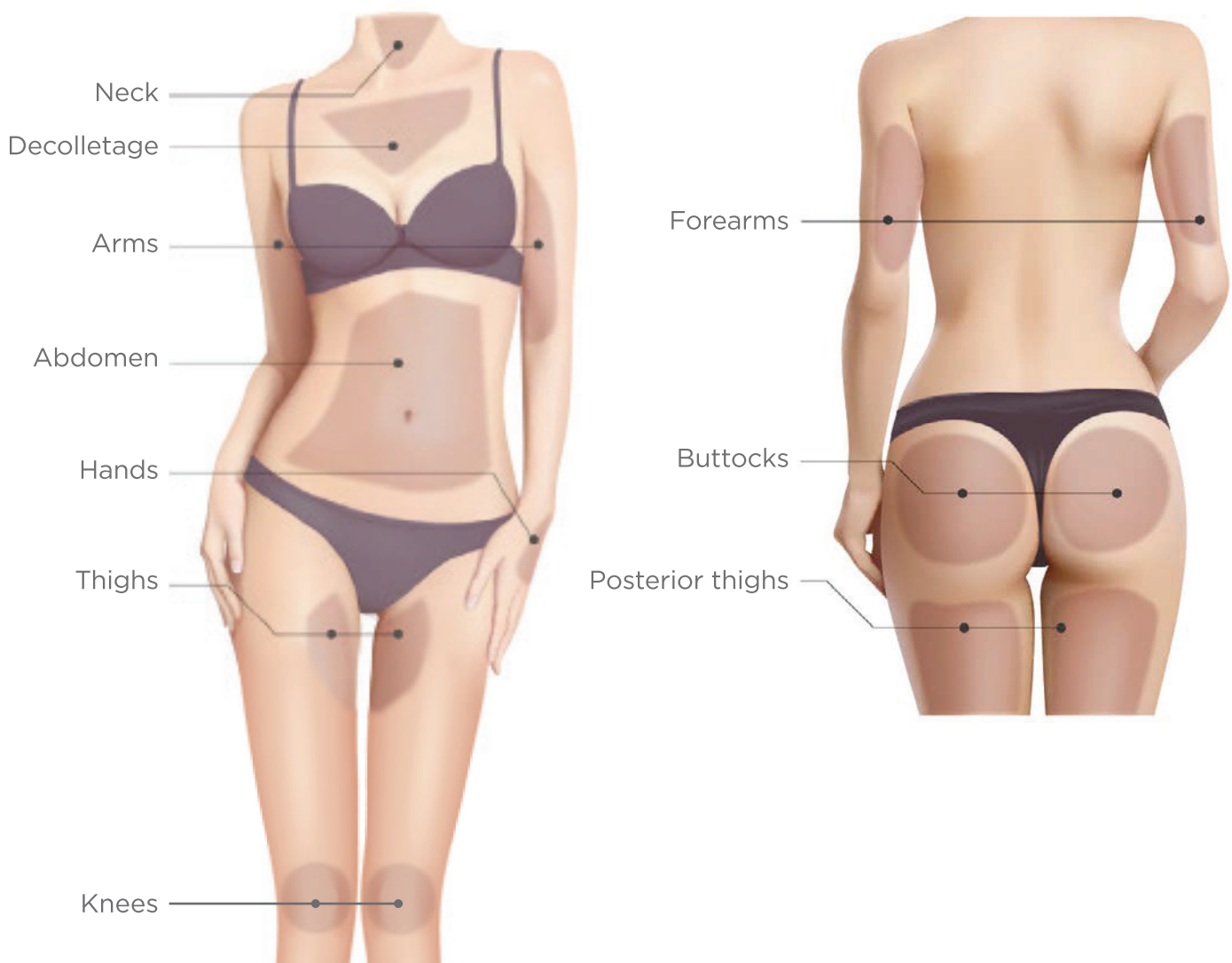


7 months after treatment

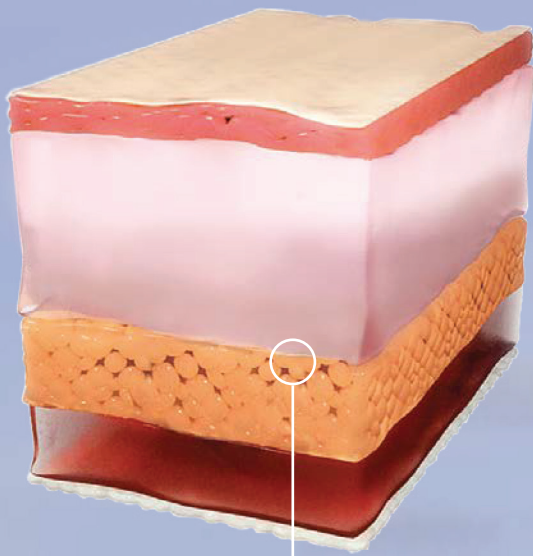
Actual patient. Individual results may vary.
Treated with 5 vials of Sculptra®,
3 sessions.

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}

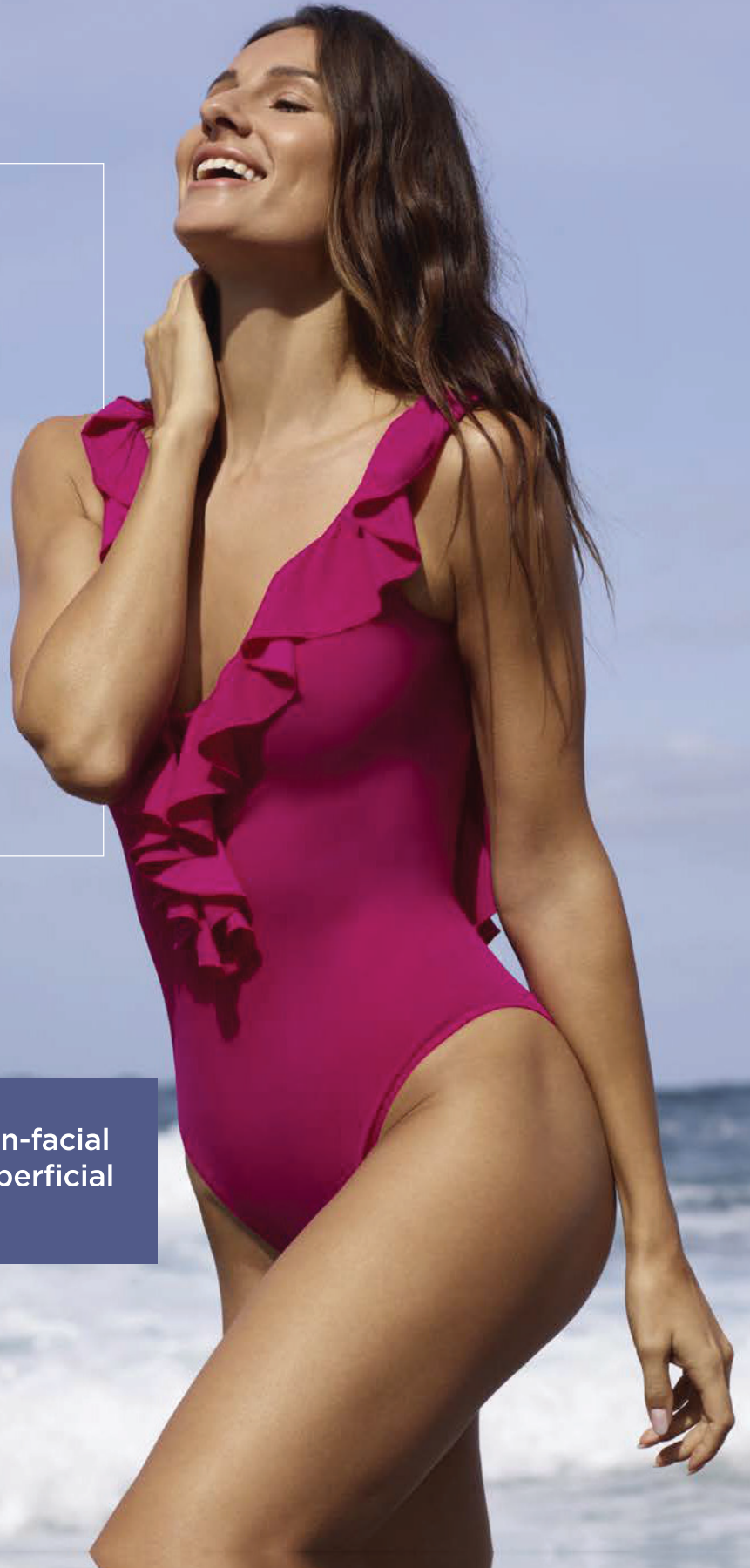


SCULPTRA® INJECTION DEPTH FOR NON-FACIAL AREAS



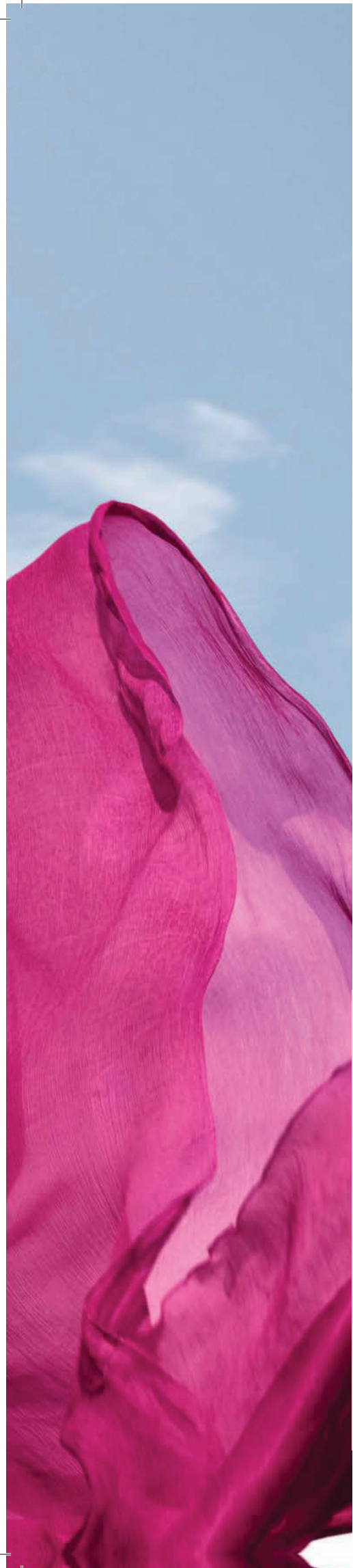
Superficial
subcutaneous tissue.

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



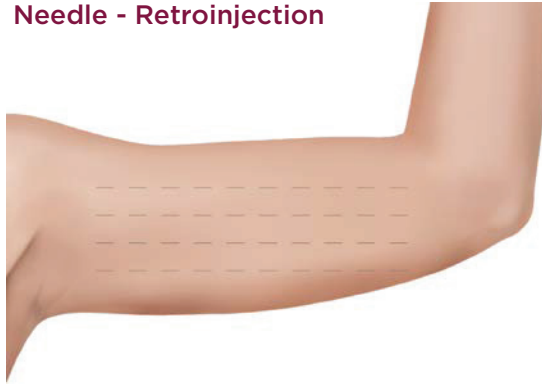
SCULPTRA[®] NON-FACIAL INJECTION AREAS AND OUTCOMES



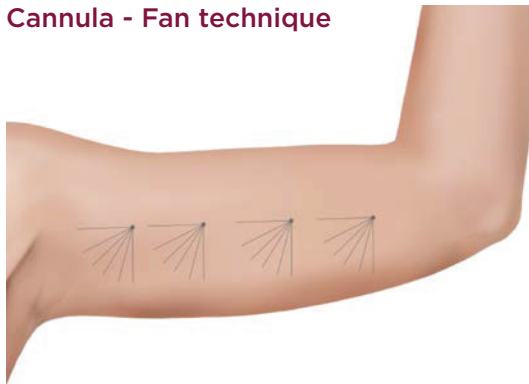


ARMS¹⁹

Needle - Retroinjection

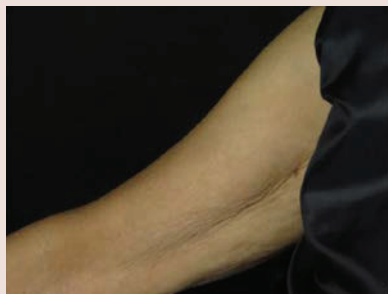


Cannula - Fan technique



Volume: 0.05 - 0.1 mL per cm²

IMPROVEMENT IN THE APPEARANCE OF SKIN LAXITY IN THE ARMS¹⁹



Before

ARMS OF A 72-YEAR-OLD WOMAN

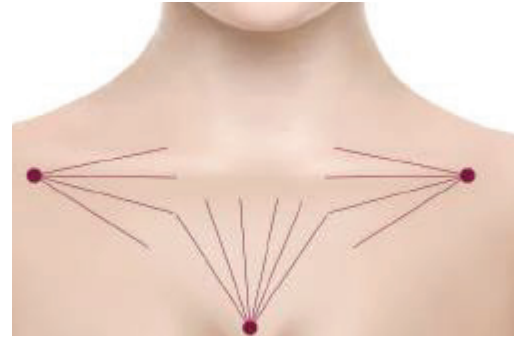
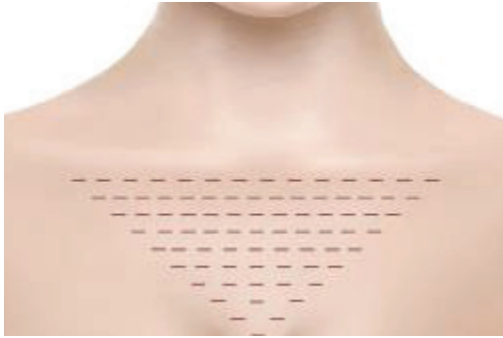
Actual patient. Individual results may vary.

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



3 months after

DECOLLETAGE



ABDOMEN¹⁹

Needle - Retroinjection



Cannula - Fan technique



Volume: 0.05 - 0.1 mL per cm²

REDUCTION OF SAGGING SKIN IN THE ABDOMEN¹⁹



Before



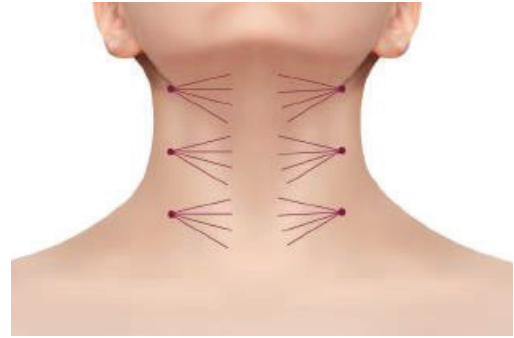
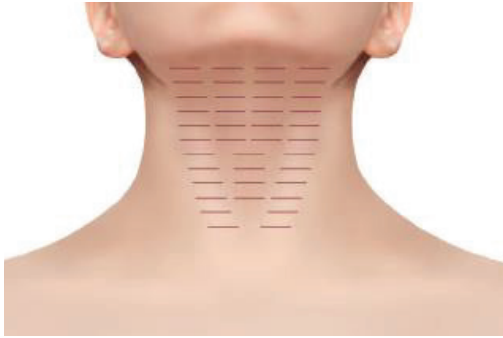
45 days after

ABDOMEN OF A 43-YEAR-OLD WOMAN

Actual patient. Individual results may vary.

Treated with 1 vial of Sculptra®.

NECK



BUTTOCKS¹⁹

Needle - Retroinjection



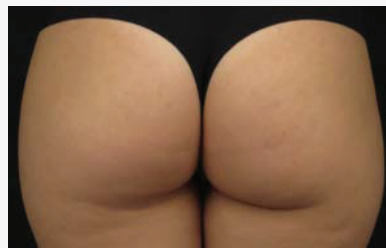
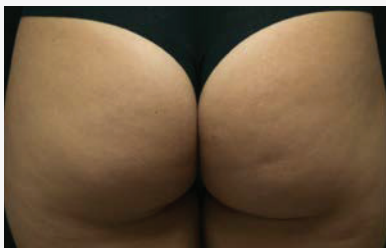
Cannula - Fan technique



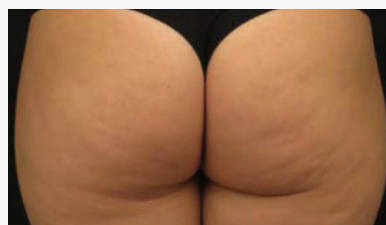
Volume: 0.05 - 0.1 mL per cm²

REDUCTION OF SAGGING SKIN IN THE BUTTOCKS¹⁹

Buttocks
at rest



Buttocks
contraction



Before

4 months after

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





AT 25 MONTHS

**HIGH
SATISFACTION**^{*53}

LONG-LASTING IMPROVEMENT
in the appearance of wrinkles^{†21}

IN MORE THAN 8 OUT OF 10 PATIENTS

*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



SCULPTRA®

REFERENCES:

1. Aziz J, et al. *Skin Pharmacol Physiol*. 2016;29(4):190-203.
2. Farage MA, et al. *Adv Wound Care (New Rochelle)*. 2013;2(1):5-10.
3. Shuster S, et al. *Br J Dermatol*. 1975;93:639-643.
4. Quan T, Fisher GJ. *Gerontology*. 2015;61(5):427-434.
5. Varani J, et al. *Am J Pathol*. 2006;168(6):1861-1868.
6. Fisher GJ, et al. *Arch Dermatol*. 2008;144(5):666-672.
7. Coleman SR, et al. *Aesthetic Surgery Journal*. 2006;26(1):S4-S9.
8. Sparavigna A. *Plast Aesthet Res*. 2020;7:14.
9. Flament F, et al. *Clin Cosmet Investig Dermatol*. 2013;6:221-232.
10. Da Cunha MG, et al. *Surg Cosmet Dermatol*. 2016;8(4):322-327.
11. Haddad A, et al. *Surg Cosmet Dermatol*. 2017;9(1):60-71.
12. Fitzgerald R, et al. *Aesthet Surg J*. 2018;38(suppl_1):S13-S17.
13. Goldberg D, et al. *Dermatol Surg*. 2013;39(6):915-922.
14. Bohnert K, et al. *Plast Reconstr Surg*. 2019;45(5):718-724.
15. Haddad A, et al. *J Drugs Dermatol*. 2019;18(9):929-935.
16. Data on File (MA-48830).
17. Hexsel D, et al. *Dermatol Surg*. 2020;46(8): 1122-1124.
18. Lacombe V. *Facial Plast Surg*. 2009;25(2):95-99.
19. Mest DR, Humble G. *Dermatol Surg*. 2006;32(11):1336-1345.
20. Narins RS, et al. *J Am Acad Dermatol*. 2010;62(3):448-462.
21. Brandt FS, et al. *Aesthet Surg J*. 2011;31(5):521-528.
22. Redaelli A, et al. *JDD*. 2014;13(9):1057-1066.
23. Sculptra. Instructions for Use - Brazil.
24. Lowe NJ, et al. *Dermatol Surg*. 2009;35(1):344-349.
25. Mazzucco R. *J Cosmet Dermatol*. 2020;19(5):1165-1171.
26. Mazzucco R, et al. *Dermatol Surg*. 2020;46 Suppl 1:S86-S88.
27. Kollipara R, et al. *Dermatol Surg*. 2020;46(12):1623-1627.
28. Lin MJ, et al. *Dermatol Surg*. 2020;46(3):386-394.
29. Sola CA, Fabi SG. *Dermatol Surg*. 2020;46(9):1257-1258.
30. Durairaj KK, et al. *Dermatol Surg*. 2020;46 Suppl 1:S46-S53.
31. Davis DS, et al. *Dermatol Surg*. 2019;45(9):1171-1184.
32. Wilkerson EC, Goldberg DJ. *J Cosmet Dermatol*. 2018;17(4):606-610.
33. Jabbar A, et al. *J Drugs Dermatol*. 2017;16(5):489-494.
34. Sadick NS, Arruda S. *Dermatol Surg*. 2017;43(2):313-315.
35. Mazzucco R, Sadick NS. *Dermatol Surg*. 2016;42(3):443.
36. Peterson JD, Kilmer SL. *Dermatol Surg*. 2016;42 Suppl 2:S101-S107.
37. Hart DR, et al. *Plast Reconstr Surg*. 2015;136(5 Suppl):180S-187S.
38. Vanaman M, Fabi SG. *Plast Reconstr Surg*. 2015;136(5 Suppl):276S-281S.
39. Vleggaar D, et al. *J Drugs Dermatol*. 2014;13(4):S44-S55.
40. Lorenc ZP. *Aesthetic Plast Surg*. 2012;36(5):1222-1229.
41. Kühne U, Imhof M. *J Cutan Aesthet Surg*. 2012;5(3):163-169.
42. Coimbra DD, Amorim AGF. *Surg Cosmet Dermatol*. 2012;4(2):182-185.
43. Bolton J, et al. *Cosmet Dermatol*. 2011;24(6):278-284.
44. Palm MD, et al. *Dermatol Surg*. 2010;36(2):161-170.
45. Rendon MI, et al. *J Cosmet Laser Ther*. 2010;12(6):284-287.
46. Redaelli A, Forte R. *J Cosmet Dermatol*. 2009;8(4):239-248.
47. Mazzucco R, Hexsel D. *Dermatol Surg*. 2009;35(8):1228-1237.
48. Sadick NS, et al. *J Cosmet Laser Ther*. 2008;10(4):237-241.
49. Schulman MR, et al. *Breast J*. 2008;14(1):92-96.
50. Ralston JP, et al. *J Drugs Dermatol*. 2006;5(10):1000-1001.
51. Redaelli A. *J Cosmet Dermatol*. 2006;5(3):233-238.
52. Rudolph C, et al. *Plast Reconstr Surg*. 2019;143(4):1077-1086.
53. Brown SA, et al. *Plast Reconstr Surg*. 2011;127(4):1684-1692.
54. Sculptra. EU Instructions for Use. June 2020.
55. Palm M, et al. *J Drugs Dermatol*. 2021;20(1):118-122.

ABBREVIATIONS:

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

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