



The Ultimate
Reshaping
Solution



 SILHOUETTE SOFT®

FACIAL ANATOMY: AGE-RELATED CHANGES

The facial ageing process is a complex interplay between different participating structures: bone, muscle, fat and skin are key elements that undergo several age-related changes

► BONES

Facial bones function as scaffolding for the overlying structure. The remodelling experienced during the ageing process, affects not only the retaining ligaments' insertion points but also the position of the overlying fat compartments. These changes lead to an alteration in the face's overall shape.

► MUSCLES

Muscles lose mass and volume, and enter into a permanent state of contraction. This, in turn, causes fat displacement from deep fat compartments around the muscles to superficial fat compartments.

► SKIN

Histological changes are mainly due to changes in the quality and quantity of collagen in the skin. In addition, skin also shifts following the displacement of deep structures within the face. This movement is stopped by the ligaments and septae between the fat compartments and causes tissue to sag and folds to deepen.

► RETAINING LIGAMENTS

Retaining ligaments hold the face's soft tissue in its natural anatomic position and so protect it from gravitational changes. However, some experts believe that the ageing process increases the laxity of these retaining ligaments, causing a lowering of the soft tissue they support.¹

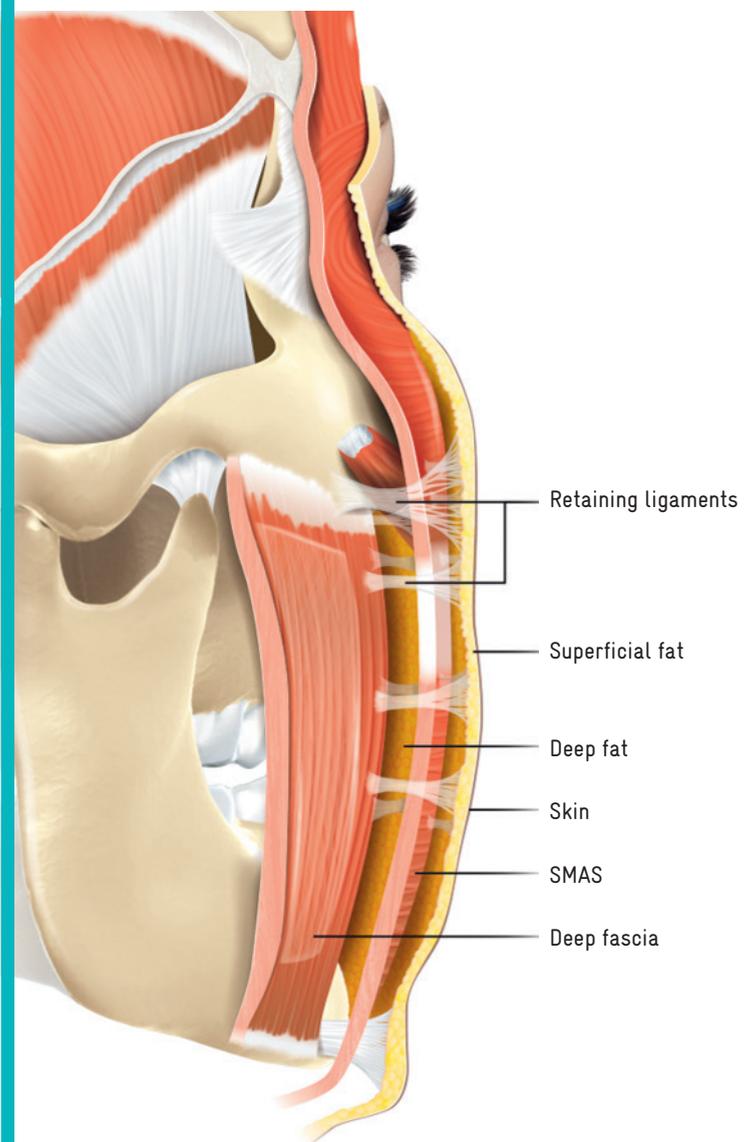


Figure 1: Skin structure

► FAT

Two types of fat have been identified in the face:

	Superficial fat layer (Hypodermis)	Fat compartments at different levels
Location	<ul style="list-style-type: none"> Uniform layer, evenly distributed Located between the dermis and the SMAS 	<ul style="list-style-type: none"> Divided into compartments Well-defined by septae Various depths
Age-related changes	<ul style="list-style-type: none"> Does not change with age Changes according to body weight Follows the displacement of deeper structures 	<ul style="list-style-type: none"> Largely affected by age Superficial fat compartments: displaced (Silhouette Soft indication) Deep fat compartments: lose 1% of volume every year from the age of 30
Treatment rationale	<ul style="list-style-type: none"> This area should be treated with other aesthetic treatments (toxin, fillers, etc.) to reduce wrinkles and improve the skin quality 	<ul style="list-style-type: none"> This area should be treated with: <ul style="list-style-type: none"> - Silhouette Soft to reposition the superficial fat compartments - Fillers to add volume to deep fat compartments

With age, superficial fat compartments slide under the force of muscle retraction, which causes tissue to sag and folds to deepen.

The nasolabial folds, marionette lines and jowls are the superficial fat compartments that are most commonly responsible for patients concern. Silhouette Soft repositions the displaced sagging fat within its compartment.

A - Nasolabial fat compartment

B - Superior jowl fat compartment

C - Inferior jowl fat compartment

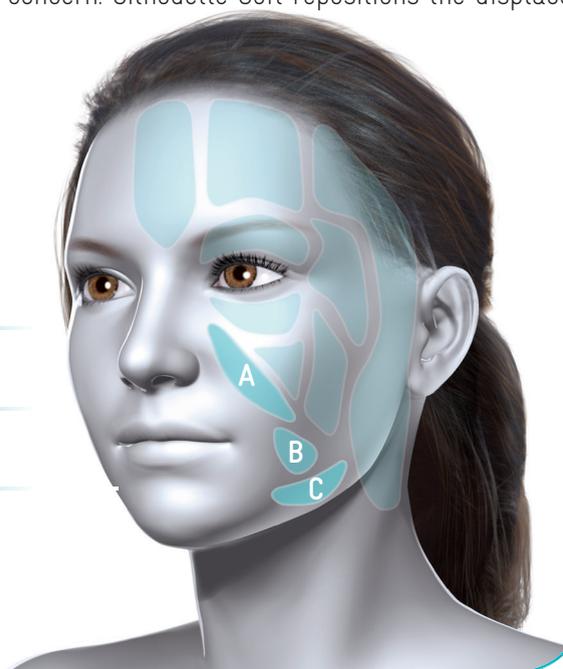
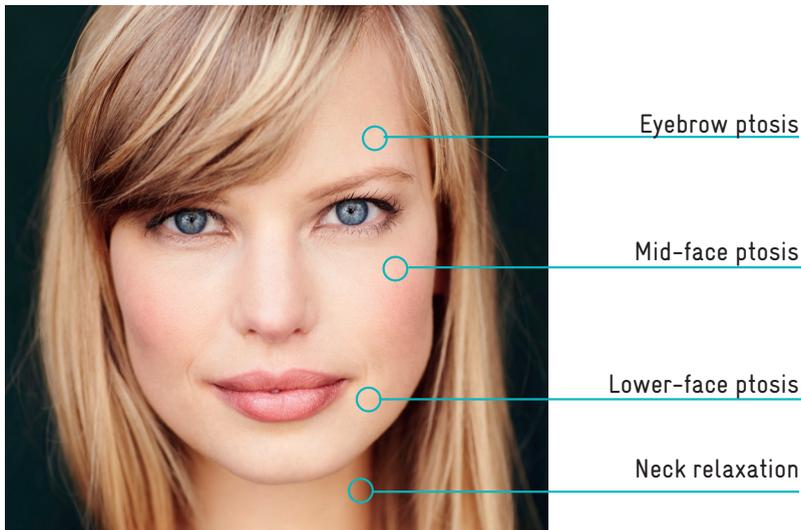


Figure 2: Superficial fat compartments

Modified from Rohrich & Pessa. Plast. Reconstr. Surg. 119: 2219, 2000

SILHOUETTE SOFT: UNIQUE FEATURES

Silhouette Soft is an innovative, resorbable suspension suture with unique cone technology. Silhouette Soft is used for the treatment of sagging skin on the mid-face, lower-face, neck and eyebrows

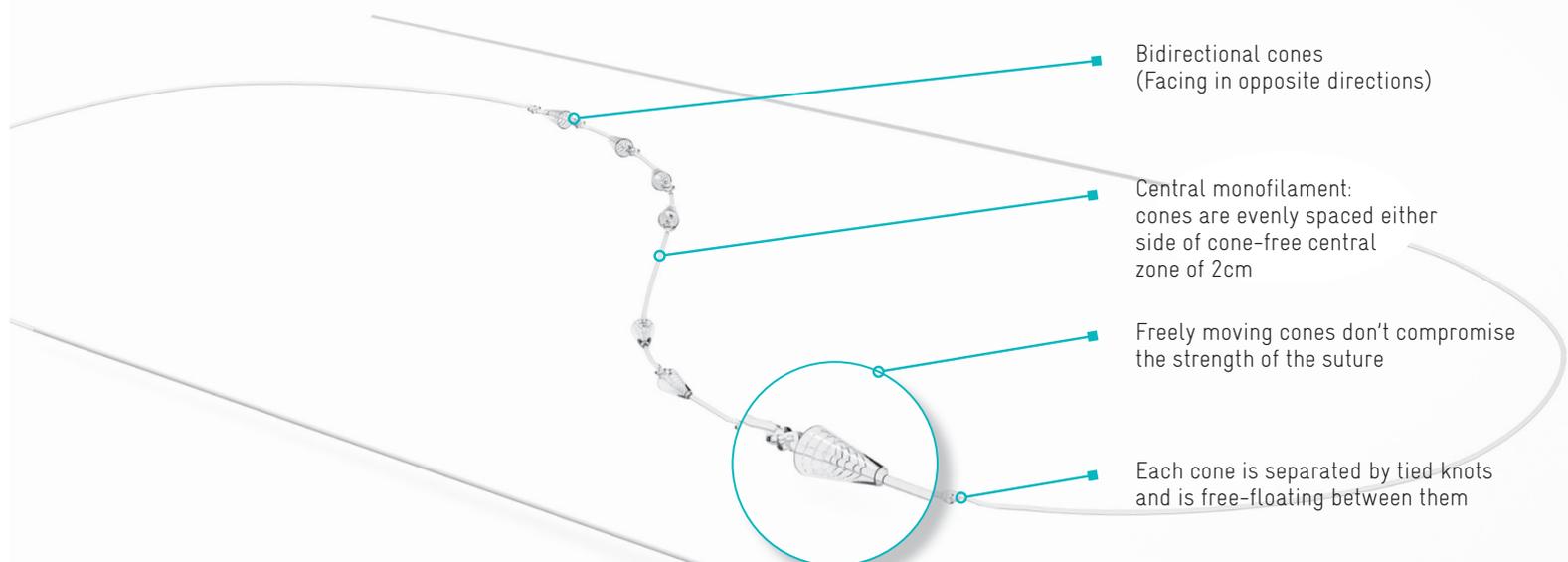


Three-product references are available in order to address different areas and degrees of skin laxity

SILHOUETTE SOFT: 8 CONES, 12 CONES & 16 CONES

► DESIGN

- **Two identical series of bidirectional cones:**
 - One series for suture fixation
 - One series for tissue suspension
- **360° surface cones:** for a stronger anchoring and better suspension capacity of the suture
- **Freely moving** cones along the monofilament, these do not compromise the strength of the suture



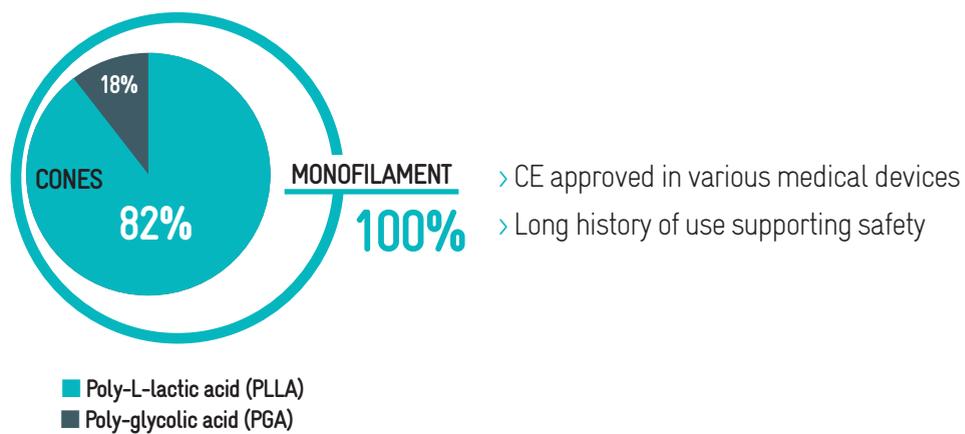
Silhouette Soft is intended to be used for facial reconstruction in the treatment, for instance, of facial lipoatrophy or morphological asymmetry. Silhouette Soft is a resorbable sterile implantable single-use device intended for adult patients and is used in multiple pairs to provide for elevation and compression of facial and neck tissue.

► COMPOSITION

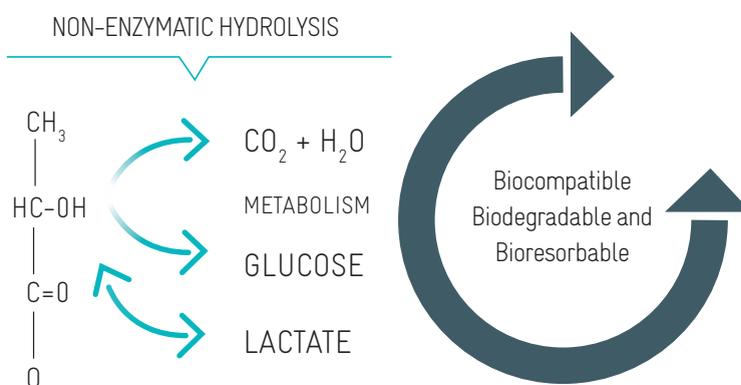
Silhouette Soft is **biocompatible, biodegradable and bioresorbable**.

The suture is composed of a monofilament made of PLLA (poly-L-lactic acid) and cones made of PLGA (82% of poly-L-lactic acid and 18% of poly-glycolic acid).

Device components



Degradation of poly-L-lactic acid (PLLA)



Degradation of PLLA occurs through hydrolysis of the polymer ester bonds which biodegrade into lactic acid. This, in turn, is removed from the body through normal metabolic pathways in the form of carbon dioxide and water.

SILHOUETTE SOFT: DOUBLE ACTION

► MECHANICAL EFFECT: IMMEDIATE TISSUE REPOSITIONING

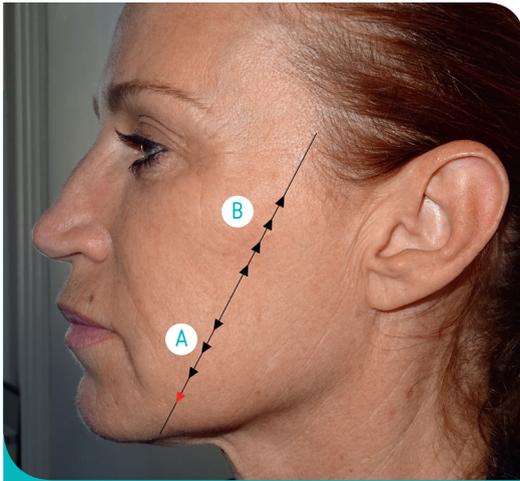


Figure 3: Bidirectional cone behaviour.
Both parts of the suture engage the tissue:

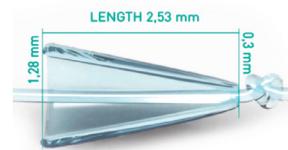
- A Elevates the tissue > repositions the soft tissue
- B Maintains results > fixates the suture to the rigid tissue

■ Bidirectional cone technology:

Provides good repositioning of mobile fat tissue and strong fixation to the rigid tissue (Figure 3).

■ Hollow cone with large 3D surface:

Ensures strong tissue engagement and efficient soft tissue suspension compared to other suspension threads.



The cone's surface area is closely linked to its tissue-holding capacity. In the same length, cones provides a surface area that is 9x greater than in barbs*.

SCIENTIFIC DEMONSTRATION

An objective comparison of Holding, Slippage, and Pull-Out Tensions for Eight Suspension Sutures in the Malar fat pads of Fresh-Human Cadaver².

■ **Objective:** To determine the efficacy and safety profile of eight suspension sutures by measuring their holding, slippage and pull-out tension.

■ **Method:** Each thread was positioned and set within the soft tissue of the cheek adjacent to the nasolabial fold and attached to a tensiometer.

■ **Results:** The cone technology provides a higher pull-out tension and higher resistance to slippage compared to barbs and cogs, ensuring greater efficiency in terms of anchorage and suspension capacity.

The 3D cone technology has demonstrated a higher pull-out tension and higher resistance to slippage compared to cogs and barbs².

* Data on file

► REGENERATIVE EFFECT: COLLAGEN PRODUCTION

■ Sustained type-1 collagen production

Silhouette Soft triggers type-1 collagen production as a result of its unique features and its interaction with the body's own tissues.

■ Long-lasting polymers

PLLA and PLGA are degraded in vivo through hydrolysis. This degradation is slow and maintained over time. Inflammatory reaction is minimal.

■ Efficient biological anchoring

A collagen capsule formed around the cone reinforces the suture's anchorage to the subcutaneous tissue.

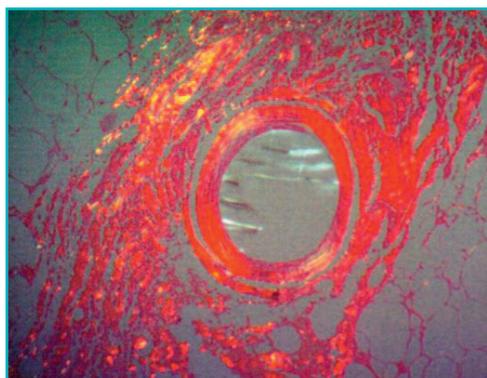


Figure 4: Biopsy taken after 12 months. Polarized light microscopy with picrosirius staining: type-1 collagen is still the predominant type present.

SCIENTIFIC DEMONSTRATION

Case Report: Histological findings after insertion of PLLA sutures with bi-directional cones in humans. Two years follow-up³.

■ **Objective:** To demonstrate the mechanism of action of PLLA sutures on a biological basis, to explain the effect on tissue repositioning and tissue regeneration as well as the improvement in skin quality.

■ **Method:** Two volunteers each had one pair of bidirectional-cone sutures implanted under the skin of their flank. Biopsies were subsequently taken at various stages over a two-year period.

■ **Results:** No adverse reaction was observed around the sutures implanted in human tissue. Histological examination has shown that PLLA sutures induce the production of new collagen, stimulated by the presence of the suture itself. An increase in type-1 collagen was evidenced in humans from 6 to 24 months after implantation. (Figure 4).

Histological examination has shown that Silhouette Soft sutures stimulate the production of type-1 collagen starting at three months and continuing through to 24 months.

SILHOUETTE SOFT: SAFETY PROFILE

■ Limited risk of suture migration or extrusion

Silhouette Soft's unique 3D cone technology provides strong anchorage to the tissue. When tension is applied, therefore, the suture remains in place and undamaged (Figure 5).



Figure 5: Pull-out Force Test (Data on file). After applying tension, Silhouette Soft sutures remain unaltered. Other products which feature barbs, however present significant damage including breakage of the barbs.

■ Limited risk of suture breakage

The freely moving cones do not compromise the strength of the monofilament and thus reduce the risk of suture damage.

■ Excellent safety profile

Adverse event rate (July 2014–August 2018): 0.022%.

The most frequently occurring adverse events are pain and swelling, that disappear within 2-3 days following the procedure.

SCIENTIFIC DEMONSTRATION

Safety and complications of absorbable threads made of poly-L-lactic acid and poly lactide/glycolide. Experience with 148 patients⁴.

■ **Method:** Data relating to complications was analysed retrospectively for 148 patients who underwent Silhouette Soft treatment between June 2014 and February 2017.

■ **Results:** Overall, 27% of patients experienced complications regarded as mild or moderate without permanent sequelae. The most common complication noted was dimpling and irregularity of the skin, followed by ecchymosis, pain and suture extrusion.

Silhouette Soft has demonstrated a good safety profile on 148 patients.
No unexpected adverse events were reported⁴.

SILHOUETTE: PATIENT SATISFACTION*

**Patient satisfaction is directly linked to patient loyalty.
A recent study confirmed a high level of patient satisfaction
following treatment with Silhouette Instalift⁵**

SCIENTIFIC DEMONSTRATION

Rejuvenating the Face: An Analysis of 100 Absorbable Suture Suspension Patients⁵.

■ **Objective:** Assess the safety, efficacy, and patient satisfaction in 100 patients treated with Silhouette Instalift.

■ **Method:** Patients who underwent a procedure using absorbable suspension suture, were critically evaluated. In addition, they anonymously completed a survey evaluating their experience.

■ **Results:** The majority of patients characterised the procedure as tolerable, immediately effective, and manageable. Most of them were pleased by the natural enhancement to their features the procedure provided.

96%

I found absorbable suture suspension to be tolerable*

79%

Overall, I am satisfied with the results from absorbable suture suspension*

82%

I would recommend absorbable suture suspension to family and friends*

83%

I found absorbable suture suspension to be an effective treatment for improving age-related changes*

*These results came from a Silhouette Instalift study. Silhouette Instalift is a similar product to Silhouette Soft.

Silhouette treatment enhances physician's practice by providing high rates of patient satisfaction.

SILHOUETTE SOFT: ENHANCED RESULTS

Understanding Silhouette Soft's biomechanical features and a careful patient selection process are essential to obtaining more effective and long-lasting results

► BIOMECHANICAL FEATURES:

■ Use the appropriate number of sutures to maximize results

The right number of sutures will ensure:

- an increase in the suspension capacity
- a lower risk of slippage, as the restoring force exerted by the repositioned tissue will be distributed more evenly among the sutures
- a more secure collagen network to support the repositioned tissue

■ Use straight-line patterns to achieve the maximum suspension traction force

Vectors need to be in a straight line and always perpendicular to the fat pad intended for treatment. Following a U-insertion pattern, the central part of the suture (2cm) effectively becomes the anchoring area. However, as there are no cones in this area, the anchoring is too weak to oppose the sum of the traction of all of the suspending cones, resulting in downward slippage of the anchoring region and loss of tension in the suture.

■ Ensure that marking is undertaken carefully

Marking, based on the position of the last cone, is a crucial step to determine the optimal placement of each suture.

A - Nasolabial fat compartment

B - Superior jowl fat compartment

C - Inferior jowl fat compartment

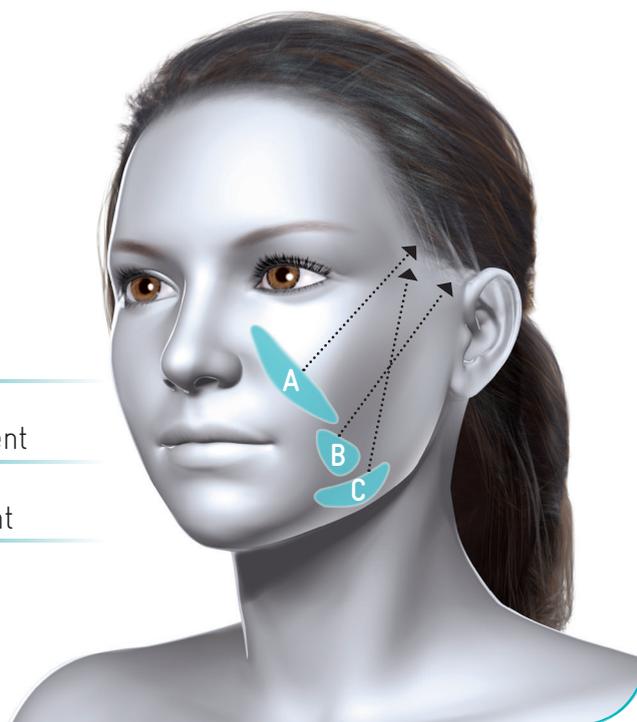


Figure 6: Facial fat compartments treated with Silhouette Soft

Modified from Rohrich & Pessa. *Plast. Reconstr. Surg.* 119: 2219, 2000

▶ PATIENT SELECTION

Patient selection criteria is key to obtain effective, natural looking and sustainable results. When selecting the patient, it is important to:

- assess the **severity of sagging**: suitable patients should present mild to moderate skin ptosis
- assess the **quality of the skin** (this should be neither too thin, nor too thick)



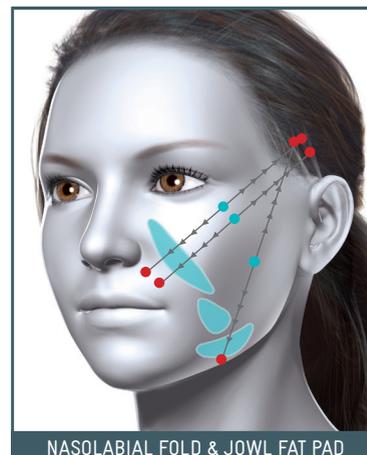
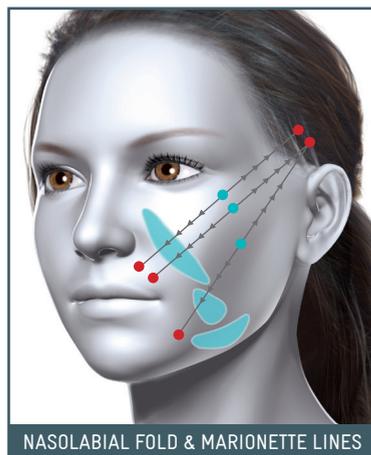
Images courtesy of Dr R. Russo, Italy

SILHOUETTE SOFT: REFERENCES & PATTERNS

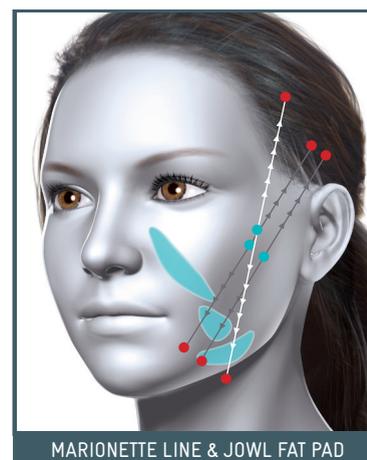
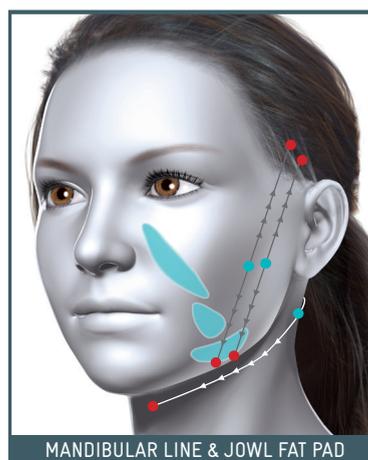
Three product references are available to address different areas and degrees of skin laxity

PRODUCT	SOFT 8 CONES	SOFT 12 CONES	SOFT 16 CONES
LENGTH	30cm	27.5cm	26.8cm
MONOFILAMENT USP /EP DIAMETER	3-0 / 2		
NUMBER OF CONES	8	12	16
SPACE BETWEEN CONES	0.5cm	0.8cm	
MONOFILAMENT MATERIAL	poly-L-lactic acid		
NEEDLE	2 needles (23G) of 12cm each		

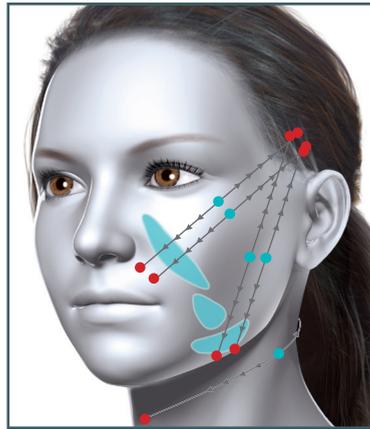
► MID-FACE TREATMENT: 6 SUTURES 3X 8-CONE SUTURE/SIDE



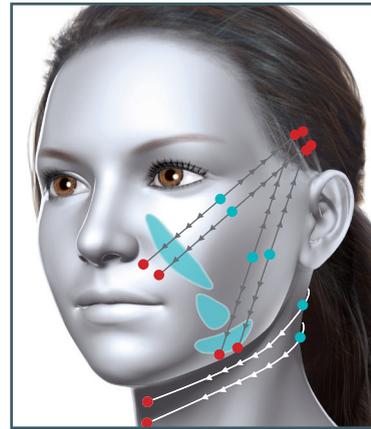
► LOWER-FACE TREATMENT: 6 SUTURES 2X 8-CONE SUTURE/SIDE 1X 12-CONE SUTURE/SIDE



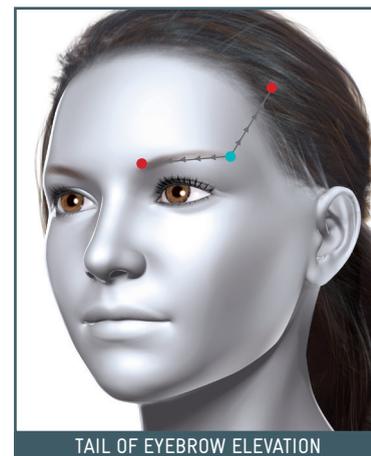
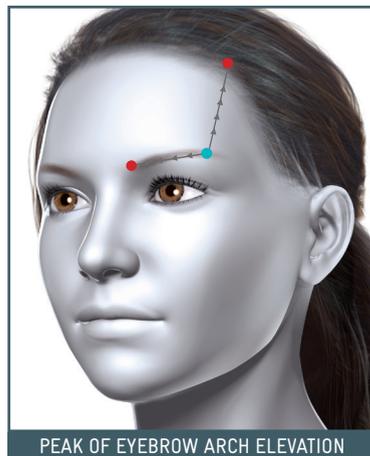
- ▶ FULL-FACE TREATMENT:
10 SUTURES
5X 8-CONE SUTURE/SIDE



- ▶ FULL-FACE & NECK TREATMENT:
12 SUTURES
4X 8-CONE SUTURE/SIDE
2X 12-CONE SUTURE/SIDE

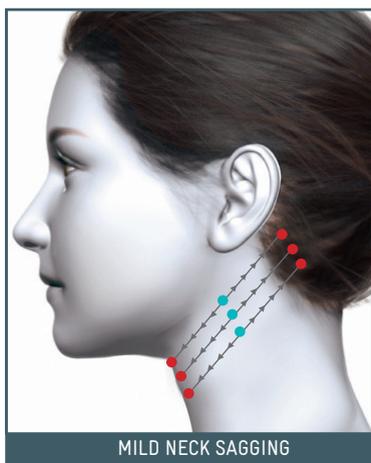


- ▶ EYEBROW TREATMENT: 2 SUTURES
1X 8-CONE SUTURE/SIDE

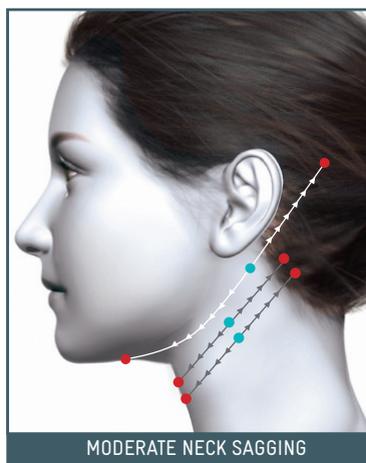


- ▶ NECK TREATMENT: 6 SUTURES

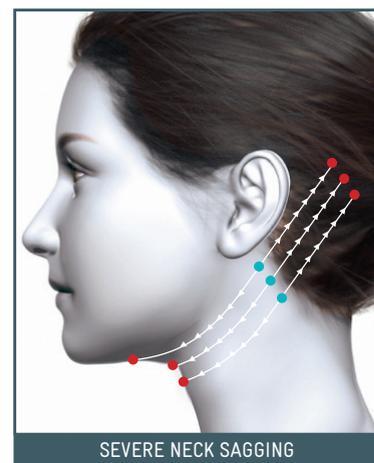
3X 8-CONE SUTURE/SIDE



2X 8-CONE SUTURE/SIDE
1X 12-CONE SUTURE/SIDE



3X 12-CONE SUTURE/SIDE

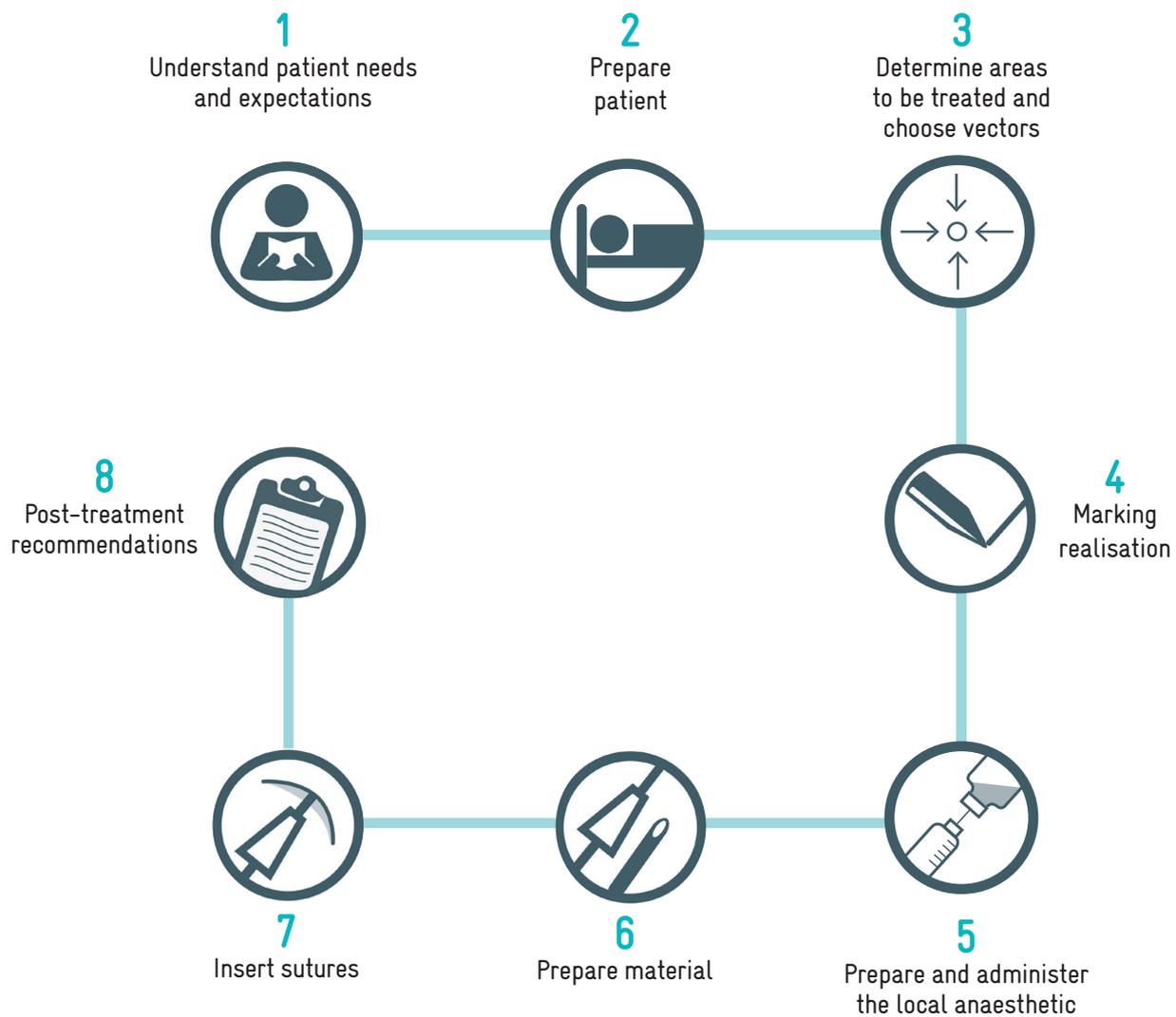


Patterns to be adapted according to patient requirements.

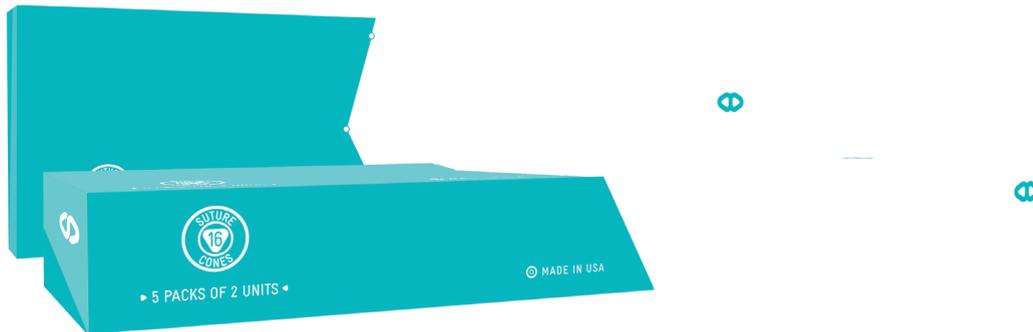
SILHOUETTE SOFT: PROCEDURE

Silhouette Soft is a non-surgical procedure, performed on an outpatient basis with minimal downtime and recovery period

► THE PROCEDURE IN EIGHT KEY STEPS:



SILHOUETTE SOFT



TREATMENT AREA	REFERENCE	BOX CONTENT
Lower-face	SMS 100	6 sutures 4x 8-cone suture 2x 12-cone suture
Mid-face	SMS 102	6 sutures 6x 8-cone suture
Full-face	SMS 22 or SMS 23	10 sutures 10x 8-cone suture or 10x 12-cone suture
Full-face & neck	SMS 100 x2	12 sutures 8x 8-cone suture 4x 12-cone suture
Neck	SMS 100 or SMS 102	6 sutures 6x 8-cone suture or 4x 8-cone suture + 2x 12-cone suture

SILHOUETTE SOFT: CLINICAL CASES

► MID-FACE TREATMENT: 6 SUTURES 3X 8-CONE SUTURE/SIDE



Courtesy of Dr. R. Russo, Italy

► LOWER-FACE TREATMENT: 6 SUTURES 2X 8-CONE SUTURE/SIDE 1X 12-CONE SUTURE/SIDE



Courtesy of Dr. S.L. Lin, Taiwan

▶ FULL-FACE TREATMENT: 10 SUTURES
5X 8-CONE SUTURE/SIDE



BEFORE



AFTER 3 MONTHS

Courtesy of Dr. V. Manning, United Kingdom

▶ FULL-FACE & NECK TREATMENT: 12 SUTURES
4X 8-CONE SUTURE/SIDE
2X 12-CONE SUTURE/SIDE



BEFORE



AFTER 4 MONTHS

Courtesy of Dr. S.L. Lin, Taiwan

COMBINED TREATMENT: CLINICAL CASES

Sinclair offers a complete portfolio with distinctive and complementing products to address the main factors of ageing.

- **SILHOUETTE SOFT®** is a revolutionary 3D cone-based suspension suture that offers effective reshaping of facial and neck contours in addition to two synergistic actions: immediate and sustained tissue repositioning and gradual tissue regeneration.
- **ELLANSÉ®** is a rejuvenating filler that reshapes the face by stimulating the patient's own collagen production. A treatment that restores volume and provides natural and long-lasting results.
- **PERFECTHA®** is a tailor-made range of "Made in France" HA dermal fillers designed for wrinkle correction, facial contouring and volume restoration.

MID & LOWER-FACE TREATMENT



FULL FACE & NECK TREATMENT

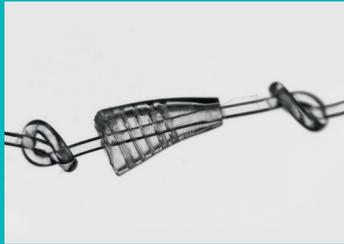


*Each product was administered in a separate treatment session allowing sufficient recovery time between each treatment. The after pictures were taken two months after the final treatment.

REFERENCES

- 1 Retaining Ligaments of the Face: Review of Anatomy and Clinical Applications.
Mohammed Alghoul. *Aesthetic Surgery Journal*, Volume 33, Issue 6, August 2013 769-782
- 2 An Objective Comparison of Holding, Slippage, and Pull-Out Tensions for Eight Suspension Sutures in the Malar Fat Pads of Fresh-Frozen Human Cadavers.
Sasaki et al. *Aesthetic Surgery Journal* 2008 28:387
- 3 Case report: Histological findings after insertion of PLLA sutures with bidirectional cones in humans: Two year follow-up.
Russo et al. *Journal of Plastic and Pathology Dermatology* 2018;14:121-125
- 4 Safety and complication of absorbable threads made of poly-L-lactic acid and poly lactide/glycolide: Experience with 148 consecutive patients.
Guduk et al. *Journal of Cosmetic Dermatology*, April 2018 10.1111/jocd.12519
- 5 Rejuvenating the face: An Analysis of 100 Absorbable Suture Suspension Patients.
M. P. Ogilvie et al. *Aesthetic Surgery Journal* 2017,1-10

SILHOUETTE SOFT: SUPERIORITY



► SILHOUETTE CONE TECHNOLOGY

- Effective tissue repositioning, large 3D surface area (2.5x larger compared to barbs area*)
- Better tissue integration, rounded and hollow-cone morphology
- Good safety profile with lower risk of migration and extrusion: the cones are freely moving and do not compromise the strength of the monofilament
- Results improve over time: demonstrated type-1 collagen stimulation

* Data on file



► BARBED THREADS

- Limited tissue repositioning, 2D barbs surface area
- Risk of surrounding tissue damage: sharp barbed-edge morphology
- Higher risk of suture migration or extrusion: barbs cut into the main filament can easily be broken as the force of the tissue is concentrated at their edges



► MOLDED BARBED THREADS

- Limited tissue repositioning, 2D molded barbs surface area
- Risk of surrounding tissue damage: sharp barbed-edge morphology
- Less homogeneous results: barbs are fixed onto the monofilament, providing less flexibility than the freely moving cones used in Silhouette products



SILHOUETTE SOFT®

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