PROFHILO®

Alma
For You. For Life.

EVERYONE IS A MASTERPIECE.

IBSA
Caring Innovation

IBSA GROUP

Founded by a group of Swiss biologists in 1945, IBSA - Institute Biochemical SA - has gained unique experience in pharmaceutical research and technology.
IBSA has used its experience and expertise in the pharmaceutical field to branch out and develop medical devices for dermatology based on hyaluronic acid - thus creating a dedicated dermoaesthetic brand: **IBSA Derma**.
IBSA Derma distinguishes itself in this vast market because it controls the entire product lifecycle, from the biofermentation production of the raw material to the ready-to-use final product in pre-filled syringes.

OVER **25** OFFICES & MANUFACTURING PLANTS

HUNDREDS OF PRODUCTS COVERING **10** THERAPEUTIC AREAS

PRODUCTS AVAILABLE IN MORE THAN **80** COUNTRIES

*"I firmly believe that **the primary role of our company is to focus on the needs of patients and healthcare professionals**, through the work of a well-trained, and above all, satisfied and motivated group."*

Arturo Licenziati

President & CEO - IBSA GROUP

IBSA DERMA

The IBSA Derma approach is aimed at countering the physiological decrease of hyaluronic acid in the skin tissue, thus restoring hydration, elasticity and tone. In fact, in a synergistic way, it combines deep hydration with mechanical action of lifting the skin.

Thanks to its innovative use of ultrapure hyaluronic acid, we can now say that **IBSA Derma has redefined the canons of classical beauty.**

In fact, throughout history, beauty has had well-defined and specific standards. Today this is no longer the case, because **IBSA Derma has redefined the beauty rules while enhancing the authenticity of each individual.**

EVERYONE IS A MASTERPIECE

IBSA Derma brings out the authentic beauty in everyone, proving that we are all masterpieces. No more faces that look the same and procedures that may distort the somatic traits, now real people are the only reference of beauty that counts.

PROFHILO®

PROFHILO®
MARKET APPROVAL

MORE THAN 2,3 MILLIONS TREATMENTS since 2015 [8].
Currently present in more than **70 COUNTRIES.**

AWARDS

2015-2016 — 3rd Anti-Aging & Beauty Trophy 2015-2016

2016 — Winner 2016 Aesthetics Awards

2017 — Aesthetics Awards Highly Commended 2017

2018 — The Aesthetic Industry Awards Aesthetic Winner 2018

2019 — Aesthetics Awards Highly Commended 2019 Injectable Product of the Year

PROFHILO®
for
BIOREMODELING

EACH BOX CONTAINS:

- 1 Pre-filled 2 ml syringe
- 1 Product leaflet
- 2 Terumo needles 29G TW 13 mm
- 2 Product traceability stickers

hydroACTION ●●●●●
liftACTION ●●●○○
CROSS-LINKING □□□□□

WHAT IS

Stabilized **Hybrid Cooperative Complexes** (HCC) of high and low molecular weight **Ultrapure Hyaluronic Acid** in high concentration, produced with a unique and innovative **thermal production process** patented by IBSA, the **NAHYCO® Technology**.

INTENDED USE

TISSUE REMODELING AND IMPROVEMENT IN SKIN LAXITY FOR:

FACE

NECK

PROFHILO®, acting through a corrective action of natural and induced cutaneous depressions, intervenes:

- in the **physiological process of aging tissue**, the effects of which include **reduced skin hydration**, the **alteration of elastic fibers** and **collagen** of the dermis, with **loss** of **turgor** and **skin tone**;
- in the **dermal tissue repair process**, in cases of acne or scars.

PROFHILO®
PRODUCTION PROCESS

STEP 1
MOLECULES COMBINED

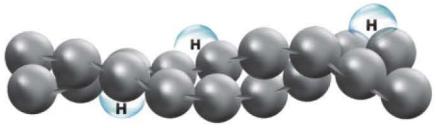
32 mg of hyaluronic acid
high molecular weight
(1100-1400 kDa)
+
32 mg of hyaluronic acid
low molecular weight
(80-100 kDa)

STEP 2
RISING TEMPERATURE

According to IBSA's patented thermal production process, the mix is heated, causing the weak hydrogen bonds (which connect H-HA molecules) to break.

NAHYCO® HYBRID TECHNOLOGY

HI + LO



NO chemical cross-linking agents used[1]

STEP 3
LOWERING TEMPERATURE

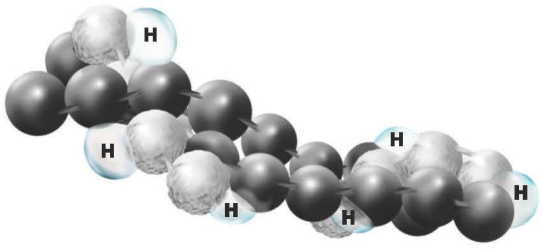
The temperature is lowered, causing the hydrogen bonds to form between the H-HA and L-HA molecules, thus creating and stabilizing the hybrid cooperative complexes.

NAHYCO®
HYBRID TECHNOLOGY

NO chemical cross-linking agents used[1]

STEP 4
A NEW MOLECULE

Stabilized hybrid cooperative complexes are obtained.



PROFHILO®

PROFHILO®
PROPERTIES & SAFETY PROFILE

HIGH HA CONCENTRATION (64mg/2ml)[1]

The highest on the market*.

HIGH QUALITY HA (ULTRAPURE)

IBSA's hyaluronic acid is an ultrapure grade HA, produced through a patented biofermentation process, of Streptococcus Zooepidemicus, which ranks worldwide as "TOP HIGH QUALITY" in terms of purity and safety.

SHYALT® ULTRAPURE
SODIUM HYALURONATE ALTERGON

BIOCOMPATIBILITY & TOLERABILITY

Thanks to NAHYCO® technology it is 100% free of chemical stabilizing agents and it presents exceptional biocompatibility and tolerability[2].

DEGRADATION PROCESS

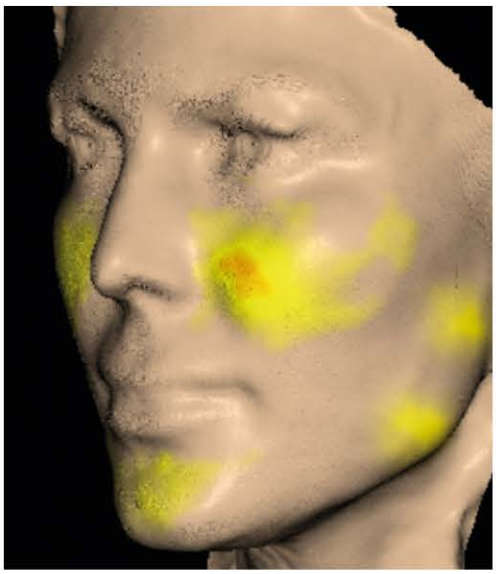
Hybrid Cooperative Complexes (HCC) of Hyaluronic Acid are biodegradable and bioresorbable by the body.

* Survey carried out by IBSA

EXTENSIVE SPREADABILITY[3] AND LOW VISCOSITY[2]

PROFHILO®'s rheological properties make it an optimal product: particularly, a predominance of fluidity over elasticity (tan delta > 1) which is not present in cross-linked gels.

Profhilo® flowability evidence based perspective



3D images taken 15 minutes after PROFHILO® BAP Face and Neck Treatments

Images taken with 3D LIFEVIZ® mini camera from Quantificare

Visualization of volume changes using a color code in the QuantifiCare software suite.

Yellow indicates a positive change in volume from the 3D photo taken before treatment, confirming PROFHILO®'s spreadability.

Red indicates greater volume change in the points injected towards the end of the treatment.

PROFHILO®
PROPERTIES & SAFETY PROFILE

HIGH COHESIVITY AND TISSUE INTEGRATION[3]

An important characteristic owing to the high cohesivity of PROFHILO® is its optimal tissue integration capacity. Notable for its ability to flow uniformly through entire anatomic units after injection and therefore homogeneously expanding.

QUALITY CONTROL

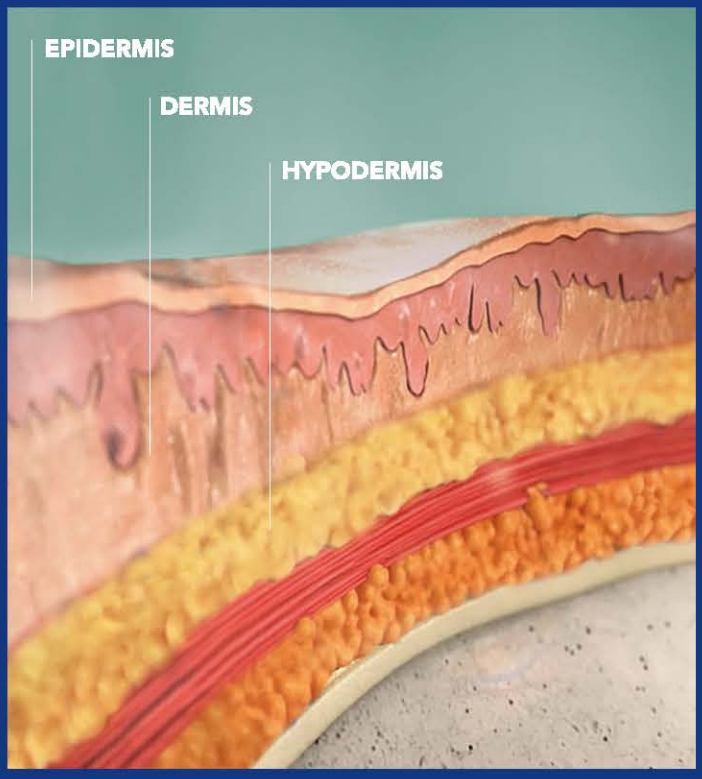
IBSA distinguishes itself because it controls the entire product life cycle, from the bio-fermentation production of the raw material to the ready-to-use pre-filled HA syringes.

PROFHILO®
HOW IT WORKS

PROFHILO® PROMOTES MULTI-LEVEL REMODELING.

It plays a role inside the extracellular matrix, creating the physiological conditions for the **proliferation, migration and organization of the dermal cellular component:**

FIBROBLASTS **KERATINOCYTES** **ADIPOCYTES**



The intradermal administration of PROFHILO® allows an optimal quantity of HA to be brought directly to the tissue being treated, in order to counteract the cytotoxic action of free radicals on the fibroblasts and on the adipose compartments below, **ensuring the efficacy of preventive and corrective aesthetic medicine treatments.**

PROFHILO®
HOW TO USE

An initial cycle of **TWO TREATMENT SESSIONS WITH A 30-DAY INTERVAL** is recommended, followed if necessary by maintenance treatments.
However, it is suggested to evaluate the specific PROFHILO® protocol according to the patient's degree of aging*.

THE BAP TECHNIQUES
(BIO AESTHETIC POINTS)

Originally created for the malar and sub-malar areas due to their predisposition to dermal atrophy caused by the aging phenomena, the BAP Technique is the most widespread and highly recommended protocol for treating these areas[4-7].

Owing to PROFHILO®'s high flowability, without leaving tissue irregularities, a specific BAP Technique was developed for the neck.

* Number of treatments and product quantity depend on the degree of aging.

REMODELING THE MALAR & SUBMALAR AREAS

These 5 points identify the 5 anatomically receptive areas of the face with an absence of large vessels and nerve branches, therefore, minimizing the risks while maximizing the diffusion of the product in the malar and submalar areas.

Identify the 5 BAP injection sites on each side of the face

Inject 0.2 ml per bolus at the superficial subcutaneous layer

1 PERI-ORBITAL MALAR REGION

at least 2 cm away from the external corner of the eye

2 ZYGOMATIC ANTHERIOR PROTUSION

- draw a line connecting the nostril and tragus
- draw a perpendicular line starting from the pupil
- locate the injection point at the intersection of the 2 lines

3 TRAGUS

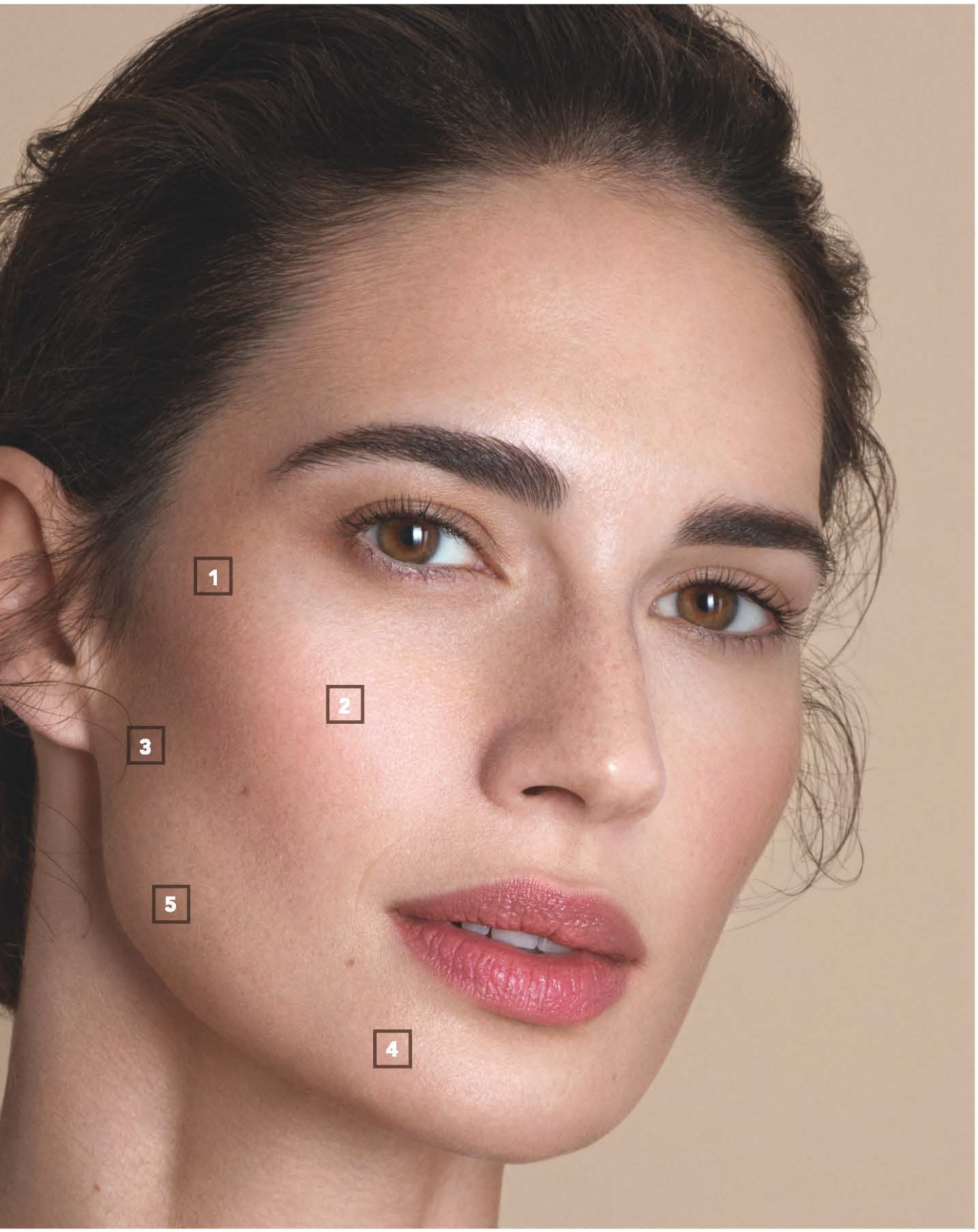
1 cm anterior to the bottom of the tragus

4 CHIN

- draw a vertical line in the center of the chin
- draw a perpendicular line one third from the top of the vertical line
- from the point of intersection move 1.5 cm towards the oral commissures

5 MANDIBULAR ANGLE

1 cm above the mandibular angle



This image is for illustrative purposes only and is intended to convey the concept and vision of the Profhilo® BAP Technique.
Do not use this image as a sole reference to perform the treatment.

NECK
REMODELING

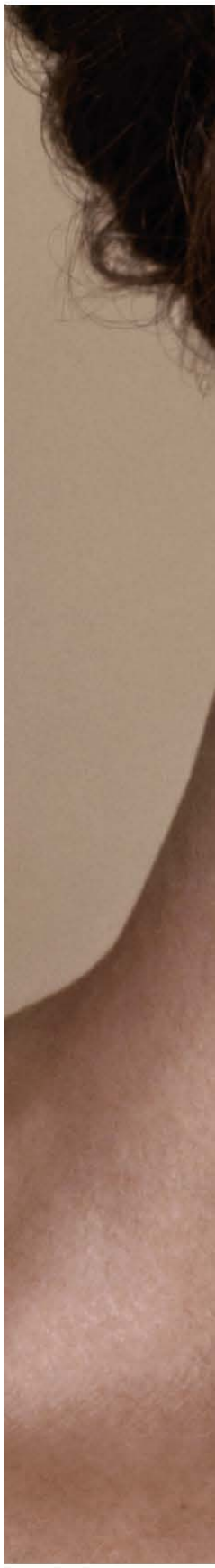
The 10 point BAP Neck Technique was developed in order to: provide reproducible points of injection, standardize these points irrespective of variations between patients and ensure that the injection points avoid potential injury to vital structures.

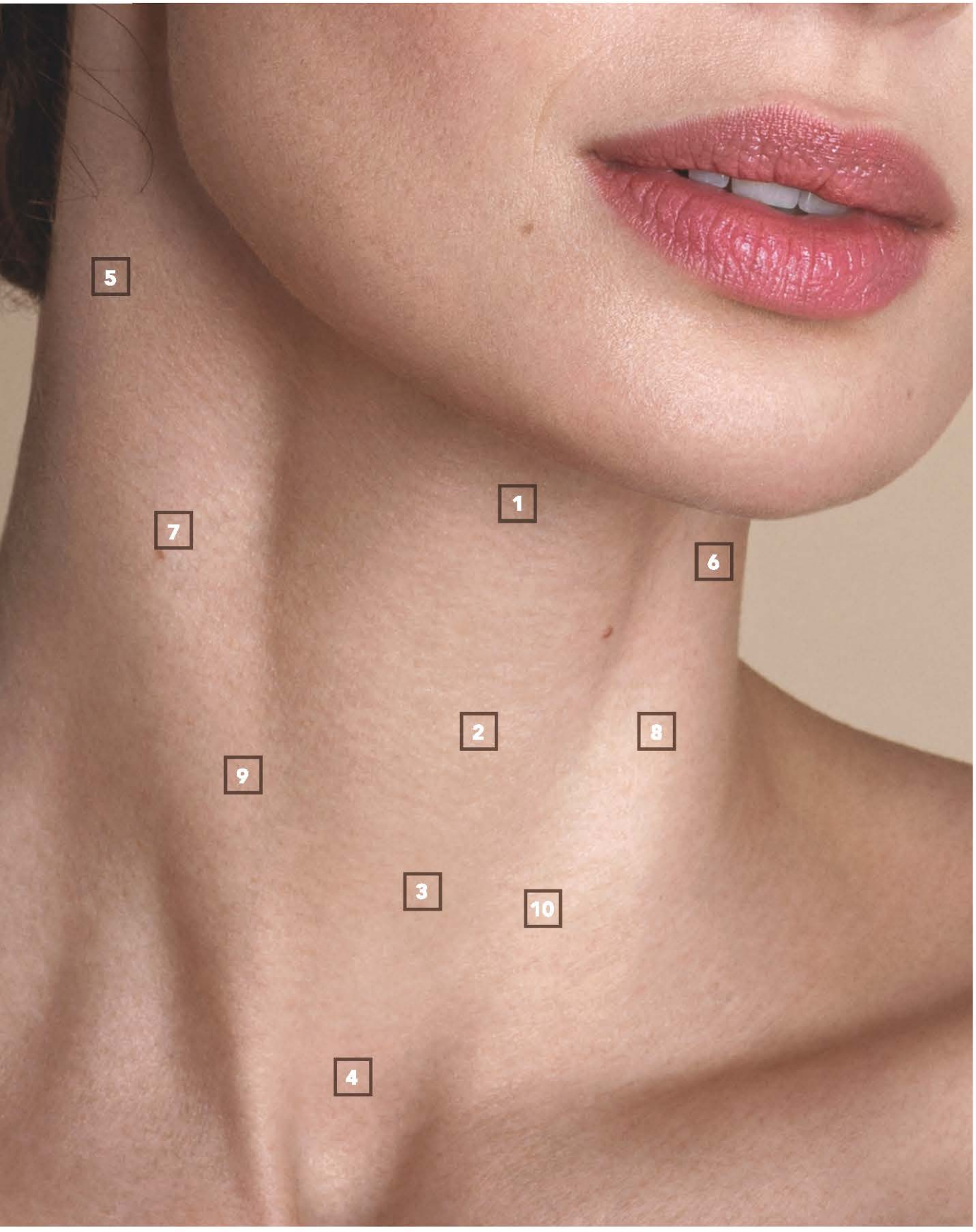
Identify the 10 BAP injection sites on the neck

Pinch the skin at the injection point

Inject 0.2 ml per bolus transversely across the skin at the superficial subcutaneous layer

1. Midline between the submental border and hyoid bone
2. Midline between the apex of Adam's Apple and bottom of thyroid cartilage
3. Midline between the base of thyroid cartilage and sternal notch
4. Midline at the apex of sternal notch
5. Horizontal line with mandibular angle & 0.5 cm lateral
6. to medial border of the SCM (sternocleidomastoid muscle)
7. Horizontal line between apex of Adam's Apple and bot-
8. tom of thyroid cartilage
9. Horizontal line between the base of thyroid cartilage
10. and sternal notch





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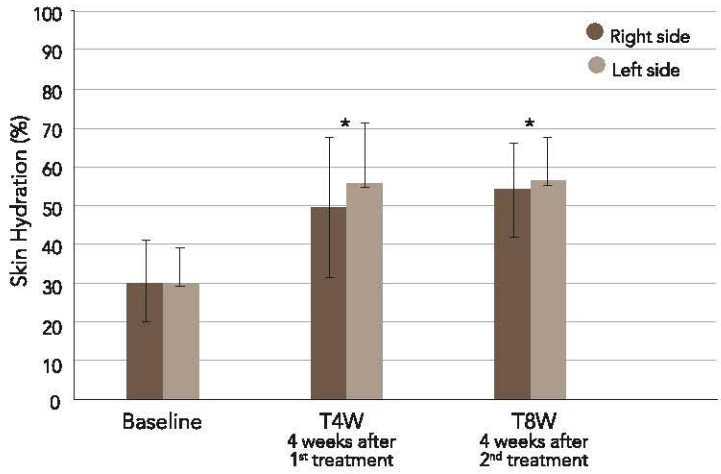
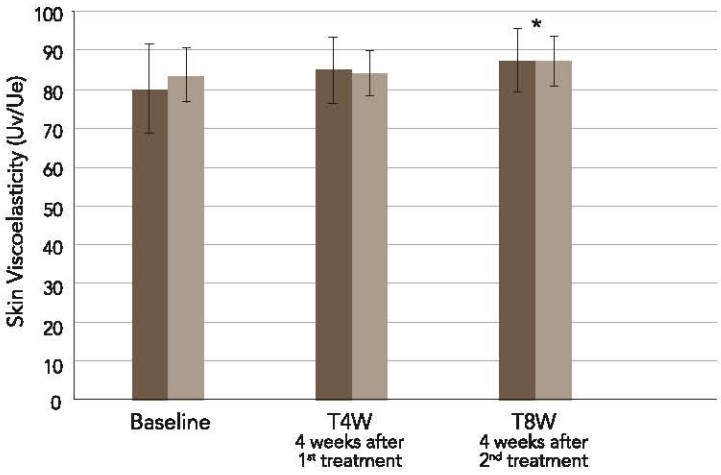
PROFHILO®
RESULTS

Improved hydration and elasticity[7]





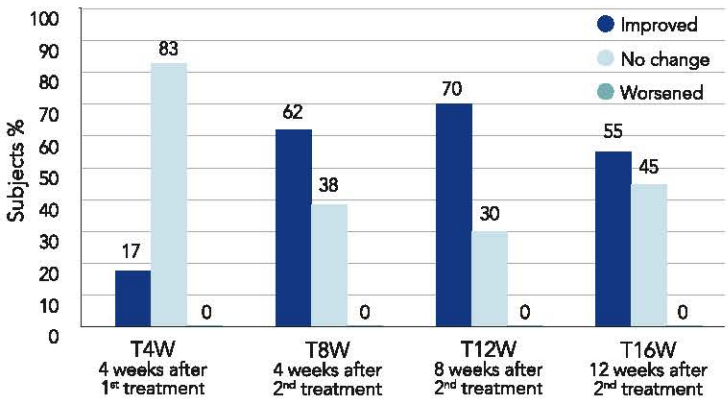
Evaluation on 15 female patients treated using BAP technique

Average age 53 yrs
(Range 39-65 yrs)

*p value <0.05

Significant improvement in skin hydration after only one treatment and in skin elasticity after two treatments

PROFHILO®'s tightening action has a positive effect on facial volume[4]



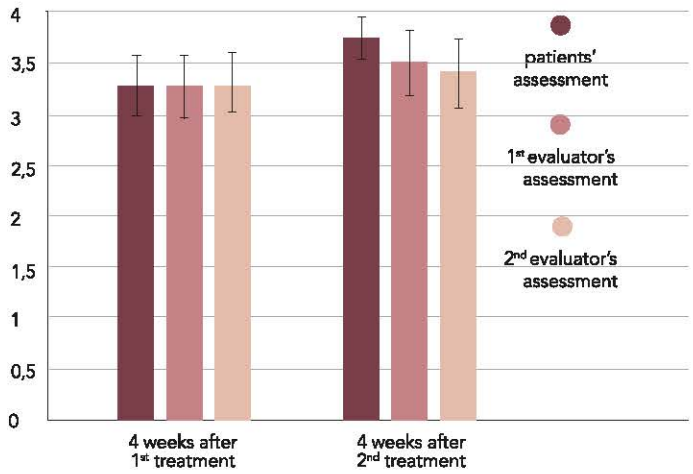
Evaluation on 64 female patients treated using BAP technique

Average age 53 yrs
(Range 38-60 yrs)

FVLS
(Facial Volume Loss Scale range 2-3)

70% of subjects show an improvement of at least one grade according to the FVLS

High satisfaction of doctors and patients[6]



Evaluation on 30 female patients treated using BAP technique

Average age 53 yrs
(Range 40-68 yrs)

Significant improvement of satisfaction levels after the second treatment

CONCLUSIONS

Profhilo® shows a significant improvement of the skin parameters and a noticeable aesthetic outcome[3].

Based on these characterizations, Profhilo® represents an intriguing new paradigm for skin restoration and improvement of skin laxity[3].

Profhilo® has significant potential for synergistic combination with conventionally cross-linked fillers to finesse volumetry results[3].

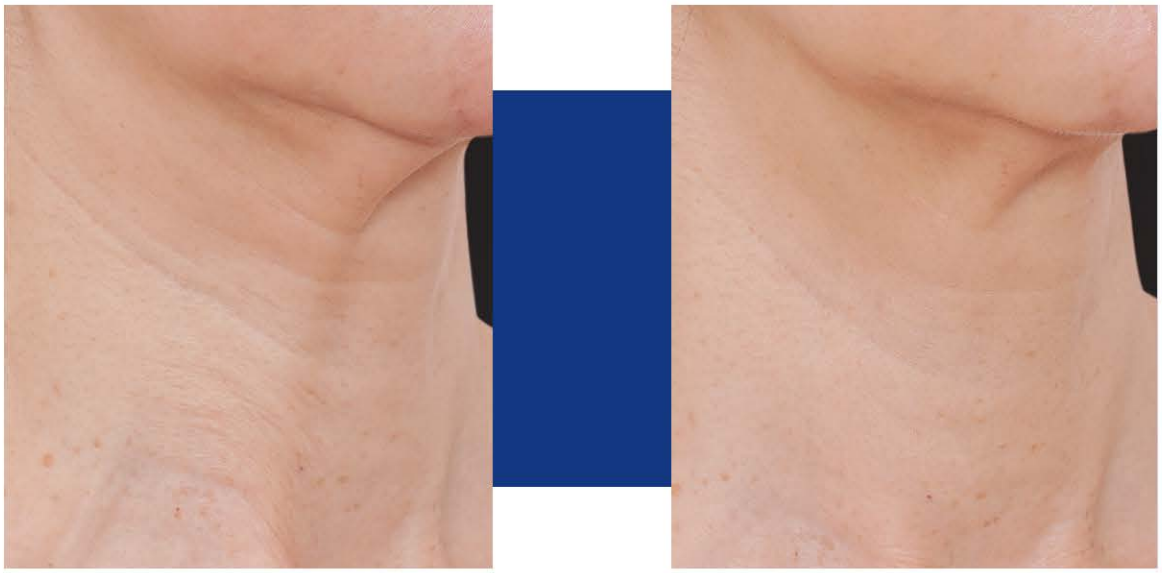
PROFHILO®
BEFORE & AFTER

Courtesy of
Dr. Elena Goltsova
(Russia)

PRODUCT QUANTITY/NEEDLE	**1 ml per side - 29G x 13mm**
TREATMENT SESSION	**2 treatments (1 month interval)**
FREQUENCY	**twice per year**

Courtesy of
Dr. Emma Ravichandran
(Glasgow, Scotland)

PRODUCT QUANTITY/NEEDLE	**1 ml per side - 29G x 13mm**
TREATMENT SESSION	**2 treatments (1 month interval)**
FREQUENCY	**twice per year**



Courtesy of
Dr. Aoi Nakano
(Japan)

PRODUCT QUANTITY/NEEDLE	**2 ml - 29G x 13mm**
TREATMENT SESSION	**2 treatments (1 month interval)**
FREQUENCY	**twice per year**

Courtesy of
Dr. Adele Sparavigna
(Italy)

PRODUCT QUANTITY/NEEDLE	**2 ml - 29G x 13mm**
TREATMENT SESSION	**2 treatments (1 month interval)**
FREQUENCY	**twice per year**

PROFHILO®
CLINICAL STUDIES

An increasing number of validated clinical studies, published in leading scientific journals.

IN VITRO CLINICAL STUDY

In vitro analysis of the effects on wound healing of high and low molecular weight chains of hyaluronan and their hybrid H-HA/L-HA complexes.
D'Agostino, et al.
Full text available on PubMed, PMID: 26163378

Hyaluronan hybrid cooperative complexes as a novel frontier for cellular bioprocesses reactivation.
Stellavato, et al.
Full text available on PubMed, PMID: 27723763

Hybrid Complexes of High and Low Molecular Weight Hyaluronans Highly Enhance HASCs Differentiation: Implication for Facial Bioremodeling.
Stellavato, et al.
Full text available on PubMed, PMID: 29179206

BAP CLINICAL STUDY

Efficacy, safety, and tolerance of a new injection technique for high and low molecular weight hyaluronic acid hybrid complexes.
Laurino, et al.
Full text available on PubMed, PMID: 26491508

Hyaluronic acid hybrid cooperative complexes and the BAP (Bio Aesthetic Points) technique: the new edge in biorejuvenation.
Beatini, et al.

Efficacy and tolerance of an injectable medical device containing stable hybrid cooperative complexes of high and low molecular weight hyaluronic acid: a monocentric 16 weeks open-label evaluation.
Sparavigna, et al.
Full text available on PubMed, PMID: 27713647

Hybrid cooperative complexes of high and low molecular weight hyaluronans (Profhilo®): review of the literature and presentation of the VisionHA project.
Agolli, et al.

SAFETY ASSESSMENT

Safety Assessment of High- and Low-Molecular-Weight Hyaluronans (Profhilo®) as Derived from Worldwide Postmarketing Data
Cassuto, et al.

IBSA
Caring Innovation

Quality Made in Italy. Quality is achieved through attention to details; not always visible, but always essential. IBSA is unique in this vast market, owing to its complete control of the hyaluronic acid lifecycle; from the raw material production to the finished product. IBSA's wide range of dermoaesthetic products, Made in Italy, is adaptable to meet various patient needs, with the goal of biorejuvenation. The knowledge, ongoing scientific research, technological development and state-of-the-art production processes makes IBSA one of the leaders in hyaluronic acid production.

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Alma
For You. For Life.

Alma is a global innovator of Laser, Light-based, Radio Frequency and Ultrasound solutions for the aesthetic and surgical markets. We enable practitioners to offer safe and effective procedures while allowing patients to benefit from state-of-the-art, clinically proven technologies and treatments.

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References

1) PROFHILO® leaflet.

2) D'Agostino A. et al. 2015; BMC Cell Biol 16:19.

3) Sundaram H. et al. 2016; Poster Presentation, American Society for Dermatologic Surgery (ASDS) Annual Meeting.

4) Sparavigna A. et al. 2016; Clin Cosmet Investig Dermatol 9:297-305.

5) Laurino C. et al. 2015; Eplasty 15:e46.

6) Rodríguez Abascal M et al. 2015; Eur Aesth Plast Surg J 2015; 5(2): 124-131.

7) Beatini A. et al. 2016; Aesthetic Medicine 2(2):45-51.

8) IBSA internal data on file YTD 05/2021.

9) Matic I. et al.: Identification of Salvia haenkei as gerosuppressant agent by using an integrated senescence screening assay. Aging 2016 - Vol. 8 December, pag 1-18.

10) Cestone E. et al.: Evaluation of the anti-ageing efficacy of Hilow Haenkenium cream in healthy woman. Aesthetic Medicine 2020 - Vol. 6; 1:25-33.

11) Cestone E. et al.: Determination of the anti-ageing efficacy of Profhilo Haenkenium cream in healthy subjects on neck and decollettè. (submitted).

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