

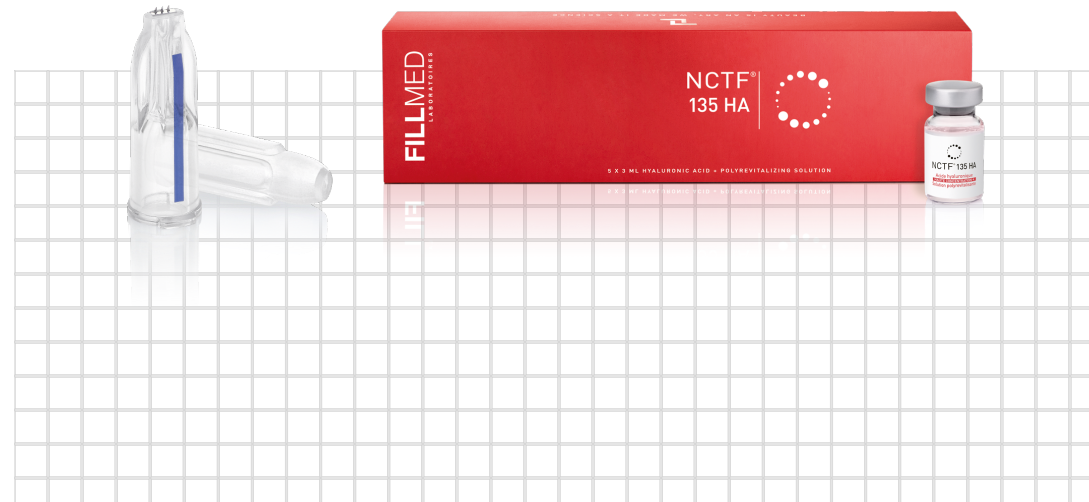
FILLMED
LABORATOIRES

TRAINING

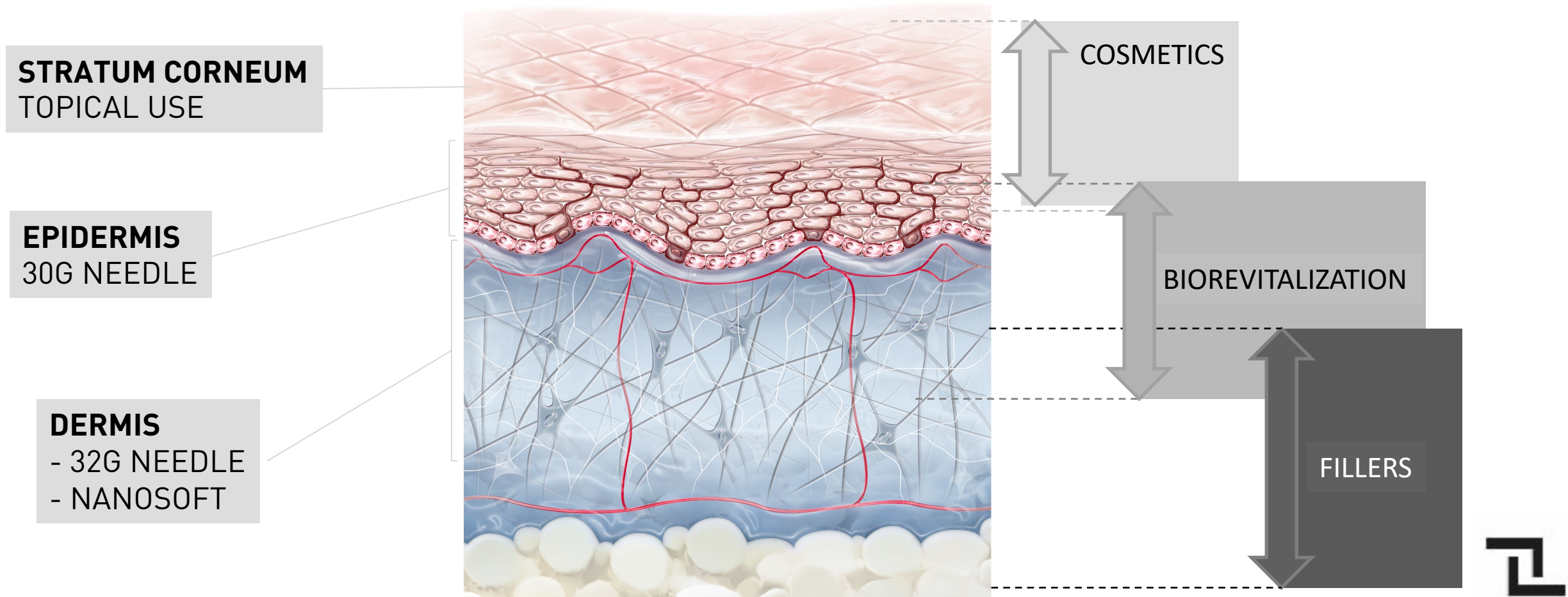


BEAUTY IS AN ART, WE MADE IT A SCIENCE

SAFETY TIPS WITH NCTF® & NANOSOFT™



MULTIPUNCTURE (epidermis and superficial dermis) MULTILAYER APPROACH





WHAT IS NANOSOFT™ ?



NANOSOFT™, INJECTION DEVICE TO TARGET THE SUPERFICIAL DERMIS

3 MICRONEEDLES, 0.6MM IN LENGTH
Equivalent to 36G each

Made of pure silicon, medical grade

EASY TO HANDLE

Blue line for injection's orientation

OPTIMAL DESIGN

Can be mounted on any standard syringe

CE MARKED



NANOSOFT™ AN EXCLUSIVE FILLMED DEVICE TO INJECT NCTF®



PACK OF 30 STERILE DEVICES

- Microneedles for superficial intradermal injection of NCTF 135 HA
- Specific device to target delicate areas: eye contour, neck, décolletage
- Minimal pain & trauma
- More accurate intradermal placement
- Predictable results





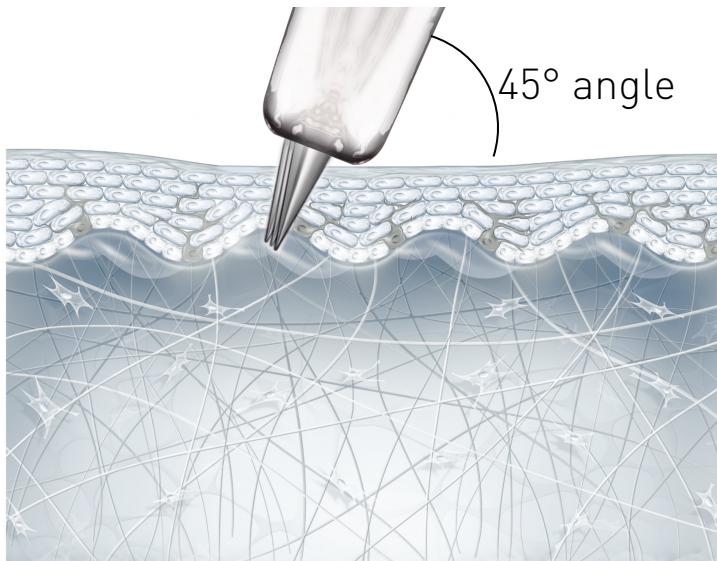
HOW TO USE NANOSOFT™?



HOW TO INJECT NCTF® WITH THE NANOSOFT™?

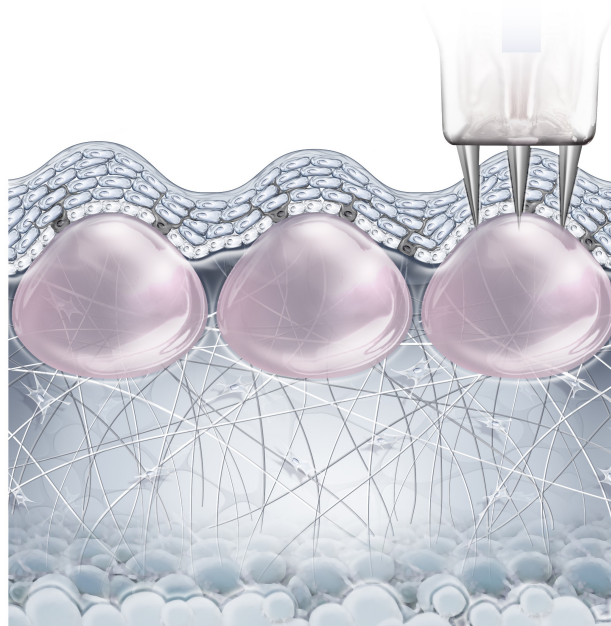
1

INJECTION INTO
THE UPPER DERMIS



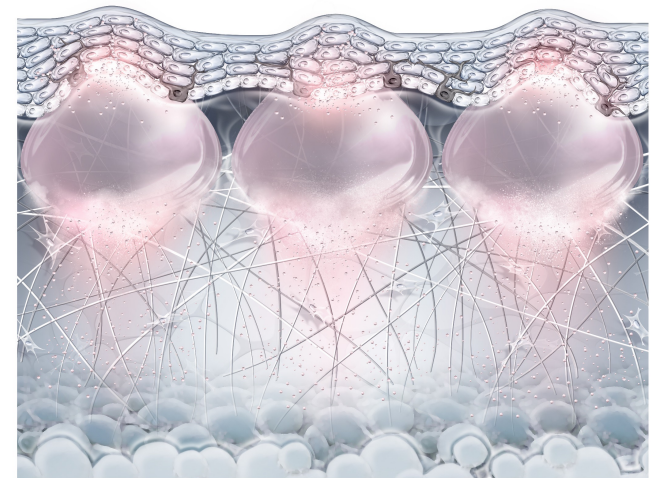
2

CREATION OF A PAPULA
IN RIGHT PLACE

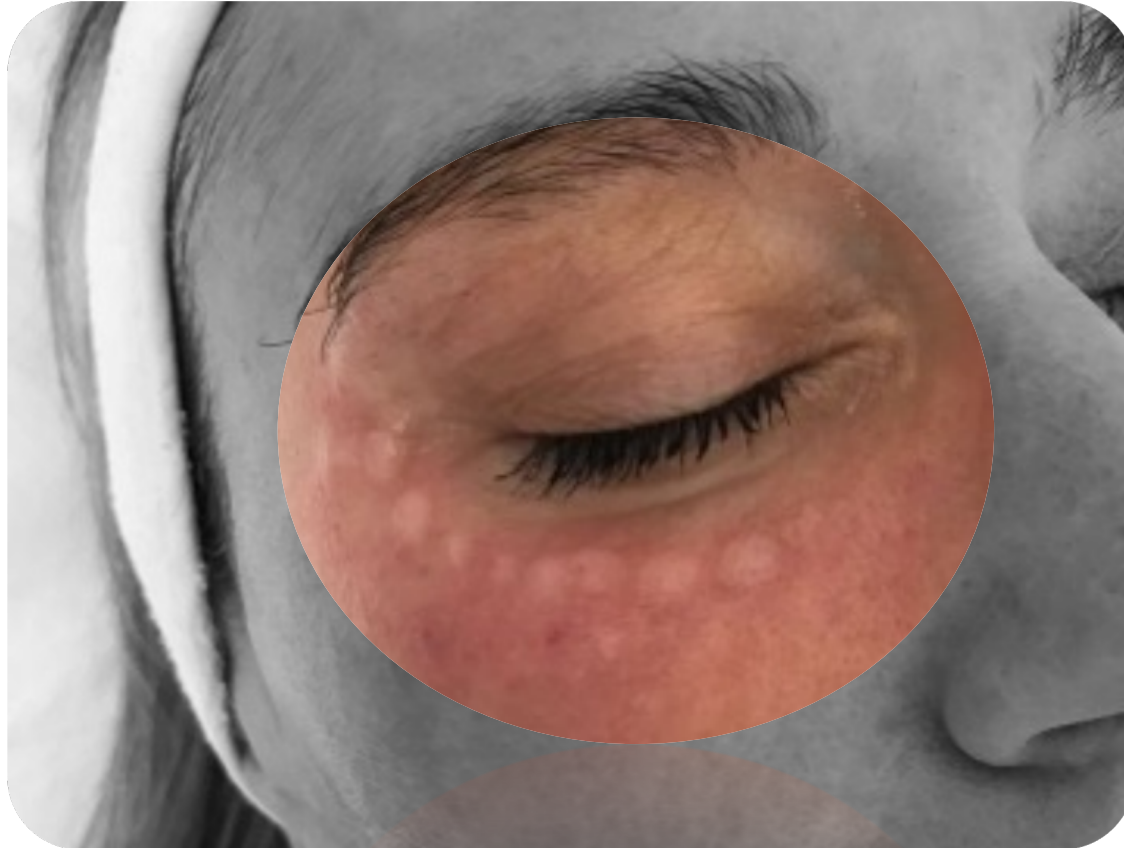


3

TIME RELEASE OF NCTF®



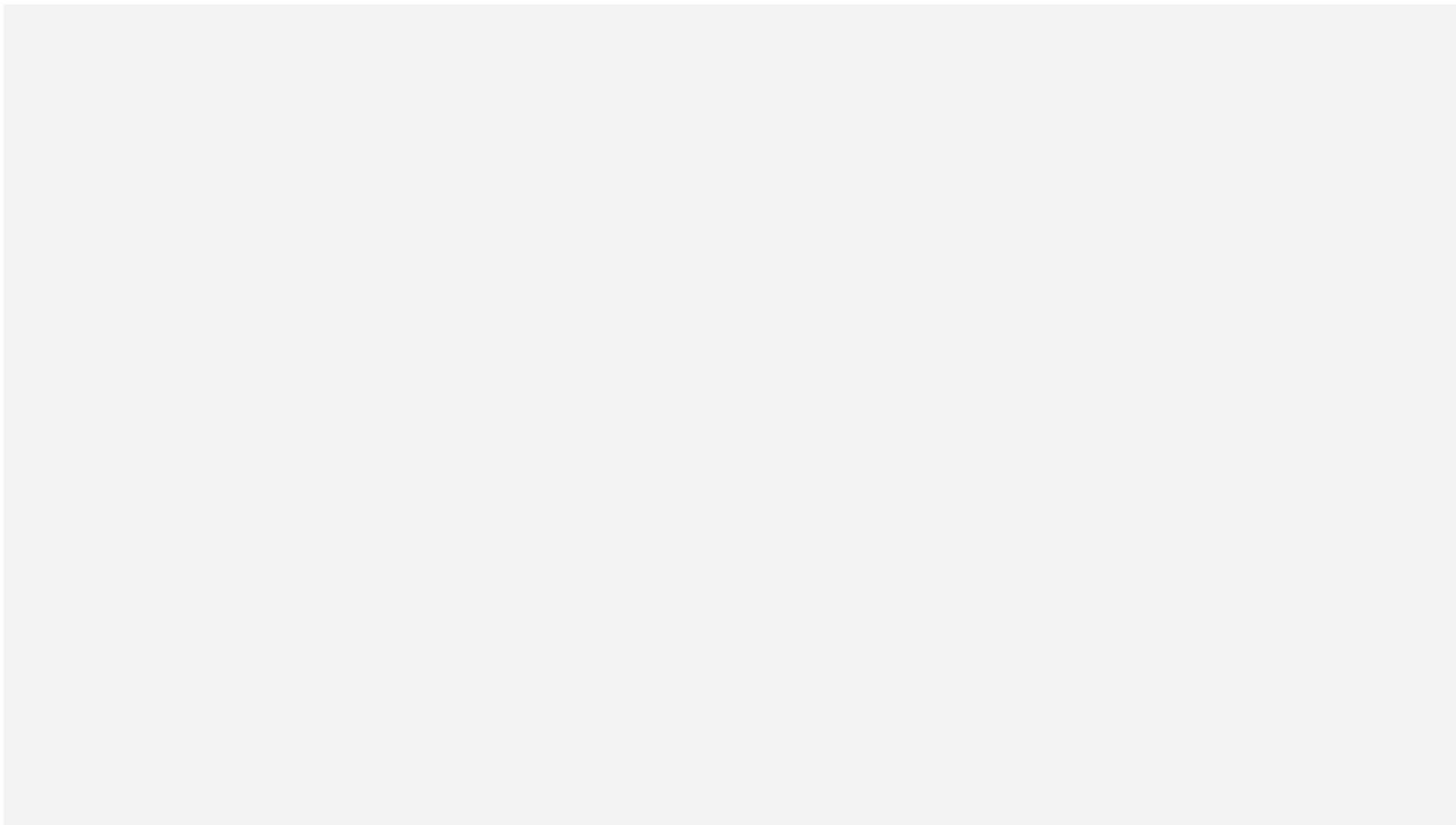
— HOW NANOSOFT™ WORKS?



The papulas of NCTF will fade away after 2 hours, and they will completely disappear after 24 hours max



— HOW TO INJECT NCTF WITH THE NANOSOFT™ ?

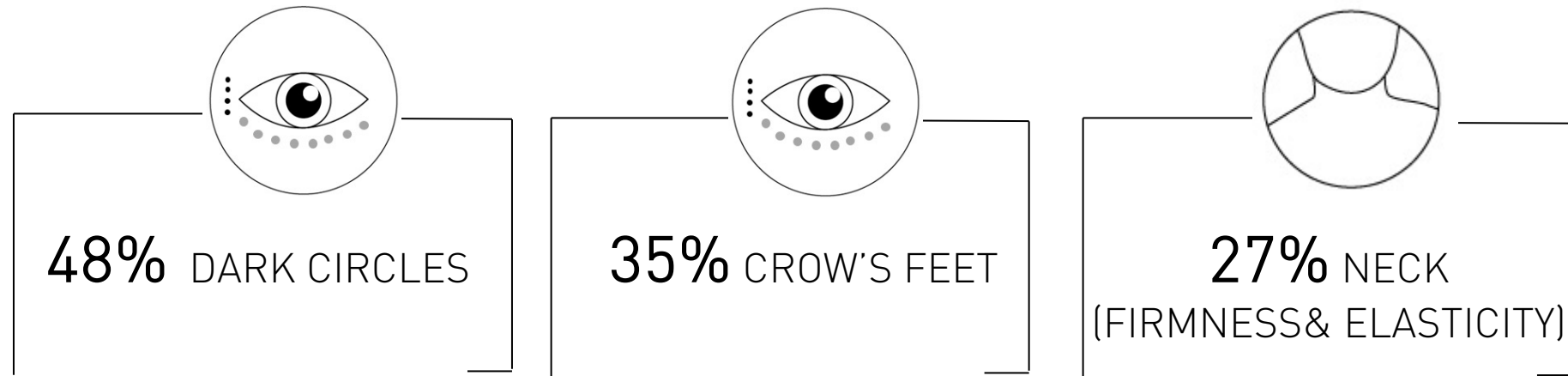




WHY NANOSOFT™?



THE DELICATE AREAS OF THE SKIN THE MAIN WOMEN CONCERNS



Delicate areas

- First areas to show ageing signs
- Continuous movement
- **Difficult to target efficiently and safely**



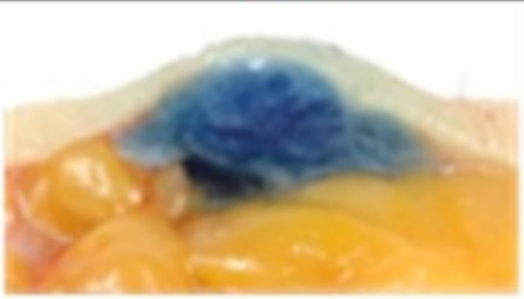
Right injection depth with Nanosoft™

Ex vivo test, classic needle vs Nanosoft™/ Cut at T5 min, T2h, T8h, T24

Classic Needle

Skin N° 6

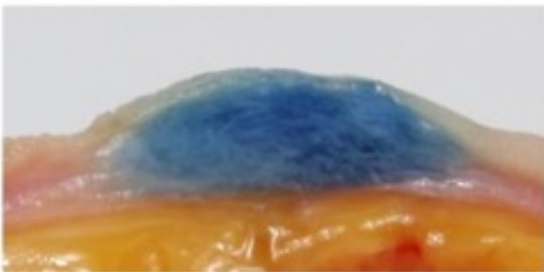
Cut at T0



Nanosoft

Skin N° 1

Cut at T0



**Injection of total face and neck
femme, 53 yo → around 100 injections!**



BEFORE



AFTER



NANOSOFT STUDY DESIGN (HEBE 3)



40 subjects



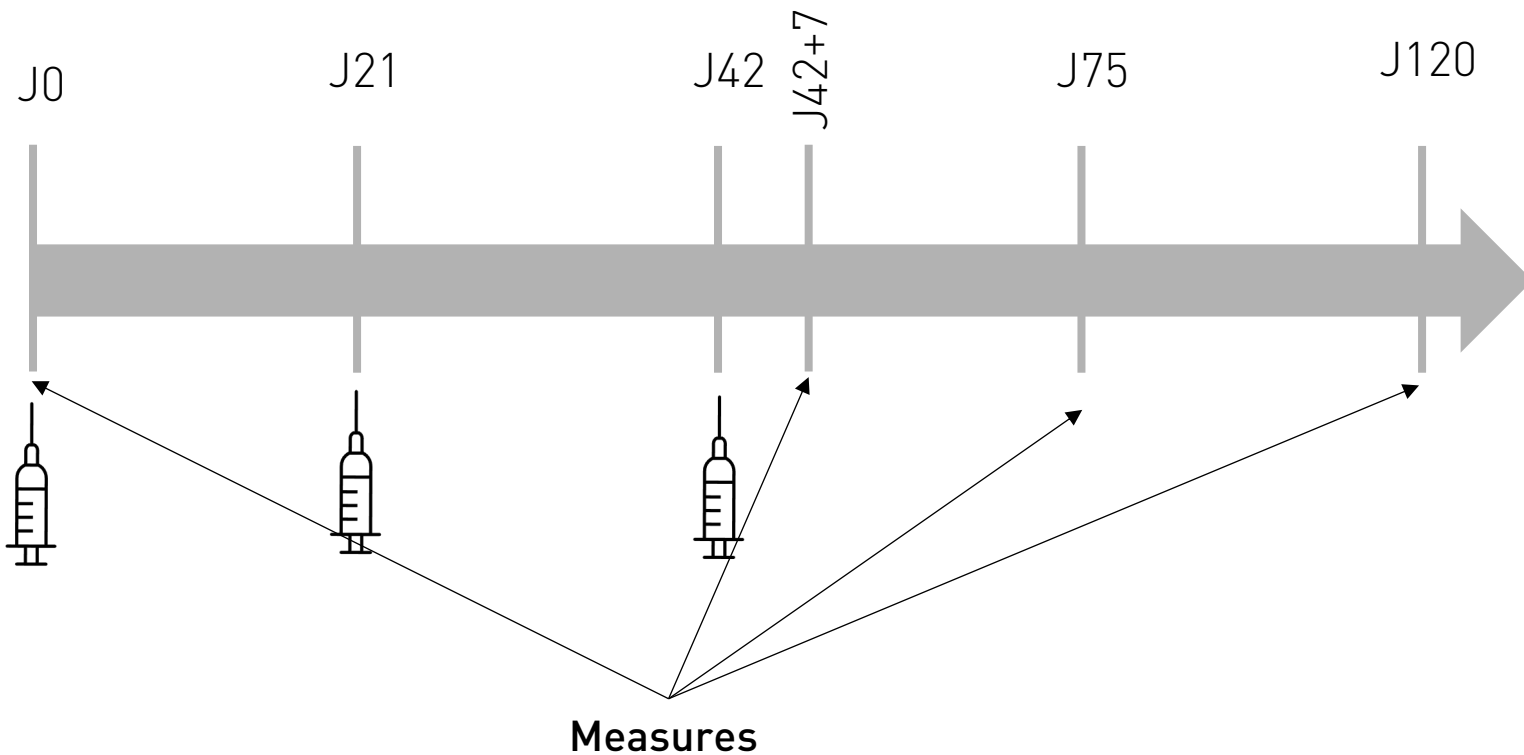
120 days (4 months)



Monocentric



3 injection sessions
3 follow-up visits

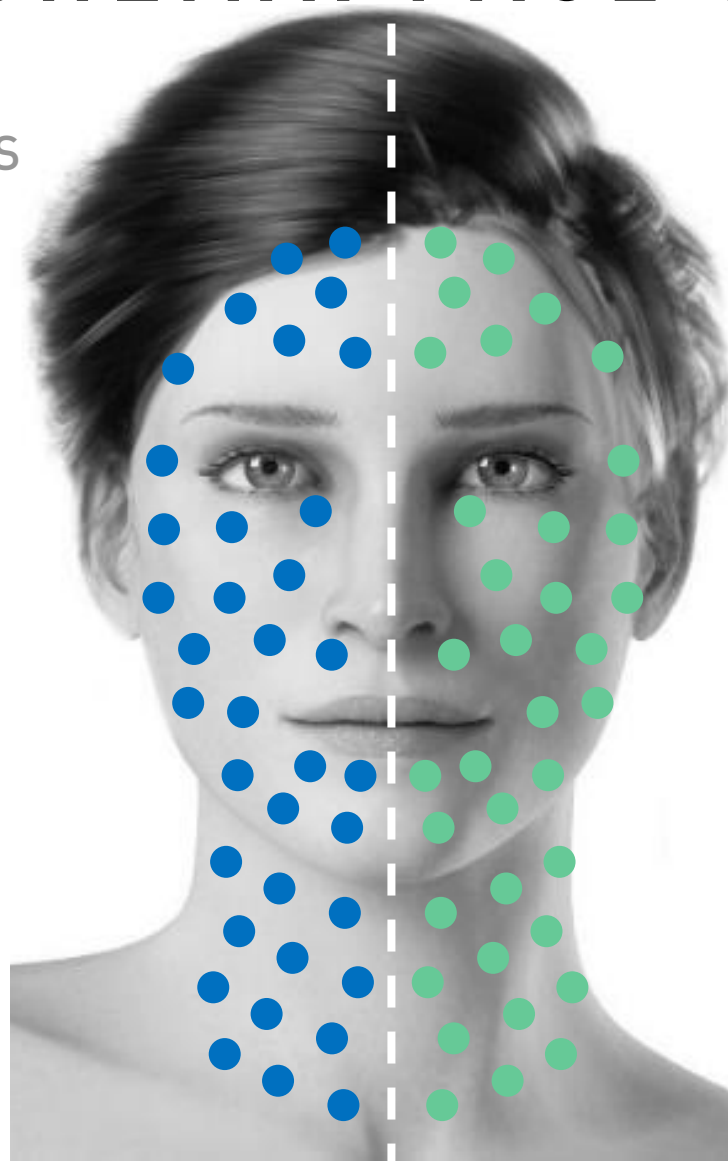


NANOSOFT STUDY DESIGN (HEBE 3) INJECTION SCHEMA: FACE & NECK

INTRADERMAL MULTI-INJECTIONS



+



+



32G



NANOSOFT STUDY DESIGN

STUDY POPULATION

Mean age : 46.9 ± 7.8

Sex : 35 female , 5 male subjects

Phototype : 0% I; 8% II; 84% III; 8% IV

Skin aging grade : All subjects enrolled had Glogau scale of 2 to 3

Previous aesthetic interventions : 85% without any aesthetic procedures

Study center : Cluj, Romania

Investigator : Pr Andreea BOCA, dermatologist



NANOSOFT STUDY DESIGN EVALUATION METHODS



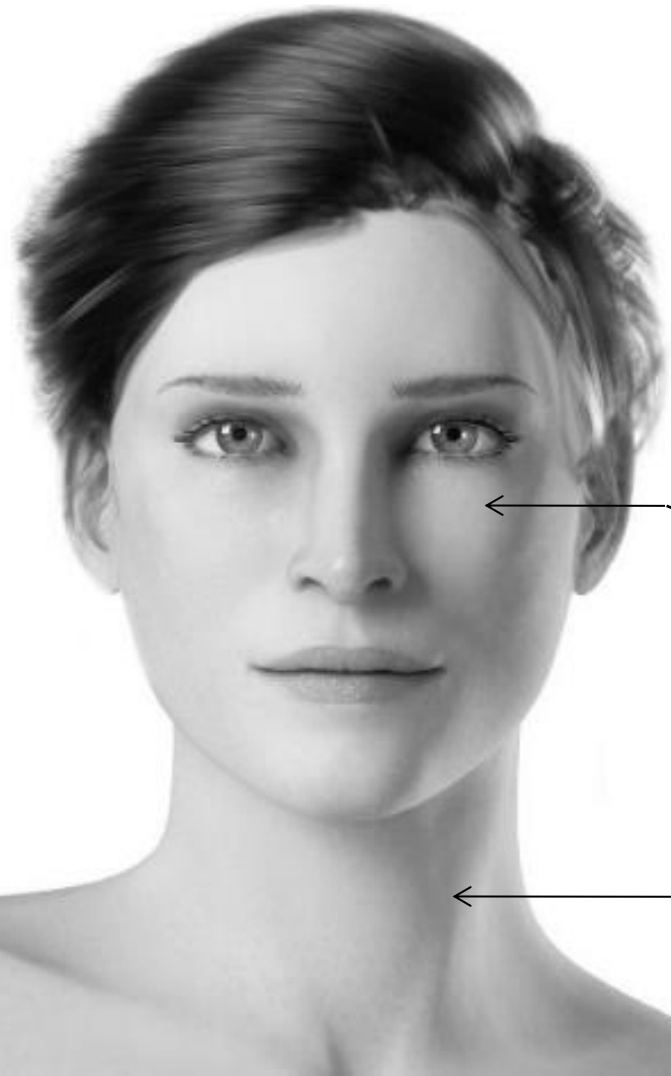
BY THE INVESTIGATORS

- CLINICAL SCORES
- INSTRUMENTAL MEASURES
- INVESTIGATOR GAIS (GLOBAL AESTHETIC IMPROVEMENT SCALE)
- TOLERANCE ASSESSMENT
- STANDARDIZED PHOTOGRAPHIES



BY THE SUBJECTS

- SUBJECT GAIS (GLOBAL AESTHETIC IMPROVEMENT SCALE)
- SELF-ASSESSMENT
- ROSENBERG SELF-ESTEEM SCALE
- DAILY REPORT OF ADVERSE EVENT



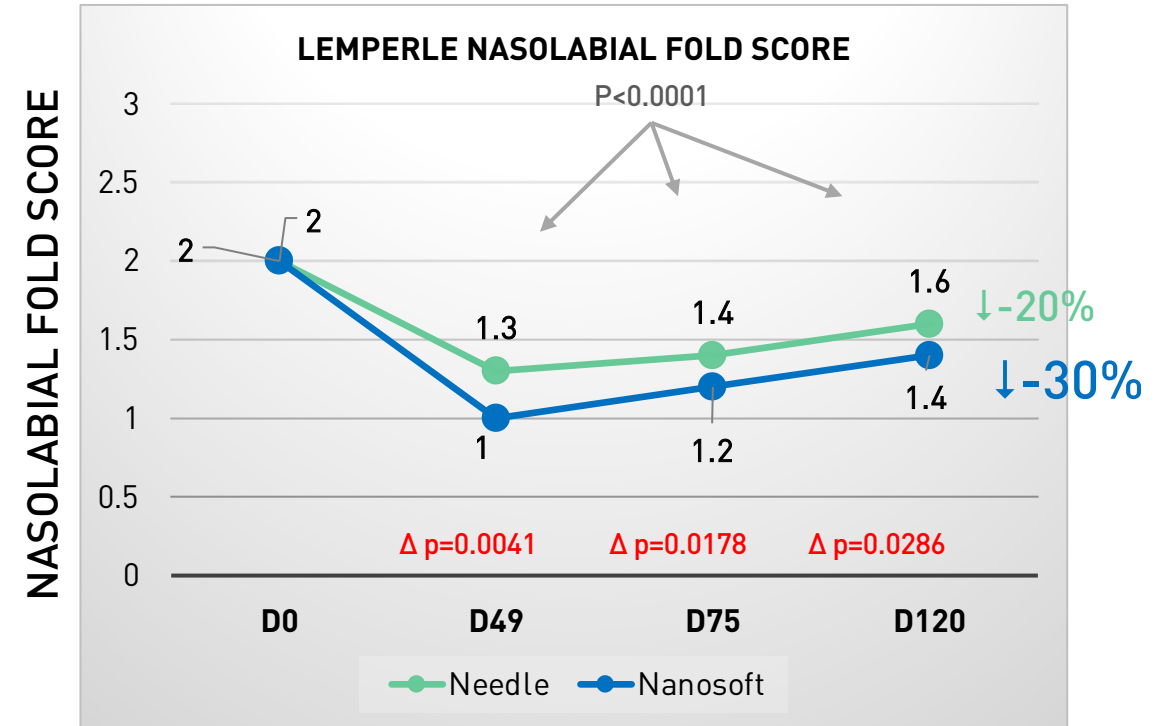
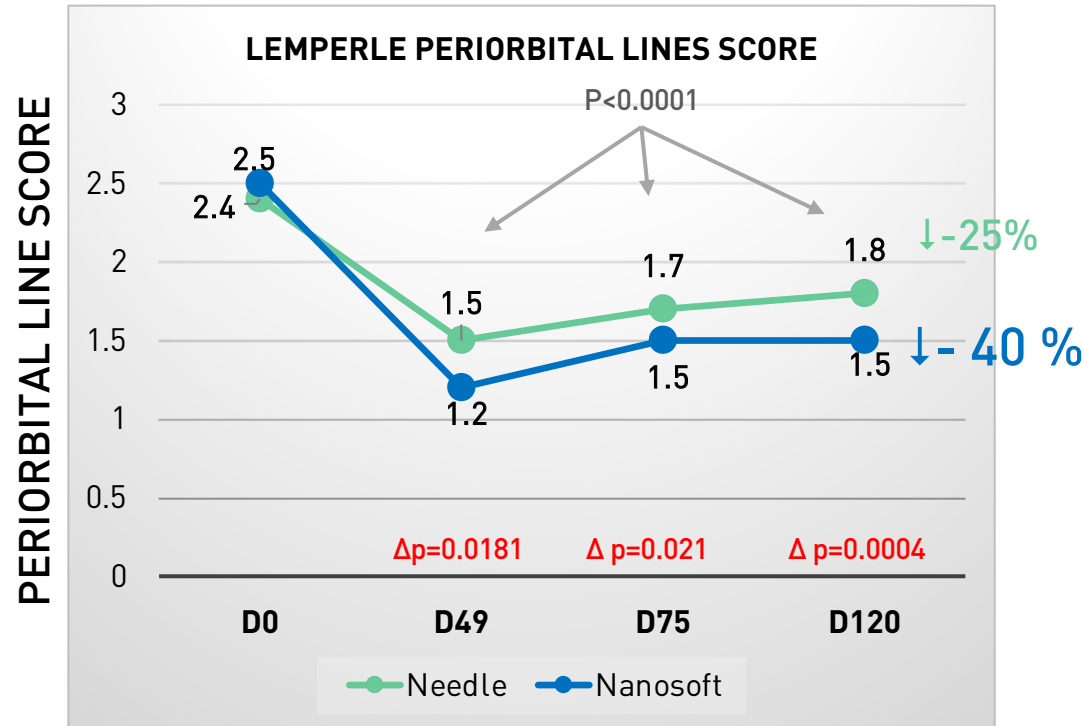
- LEMPERLE SCORE (peri-orbital, NLF)
- SKIN RADIANCE (Clinical score)
- SKIN ROUGHNESS (fringe projection by silicon replica of crow's feet wrinkles)
- SKIN HYDRATION (Dermalab®)
- ELASTICITEY (Dermalab®: viscoelasticity)

- BAZIN NECK WRINKLES SCORING
- SKIN HYDRATION (Dermalab®)
- SKIN THICKNESS (High frequency ultrasound imaging)
- ELASTICITEY (Dermalab®: viscoelasticity)



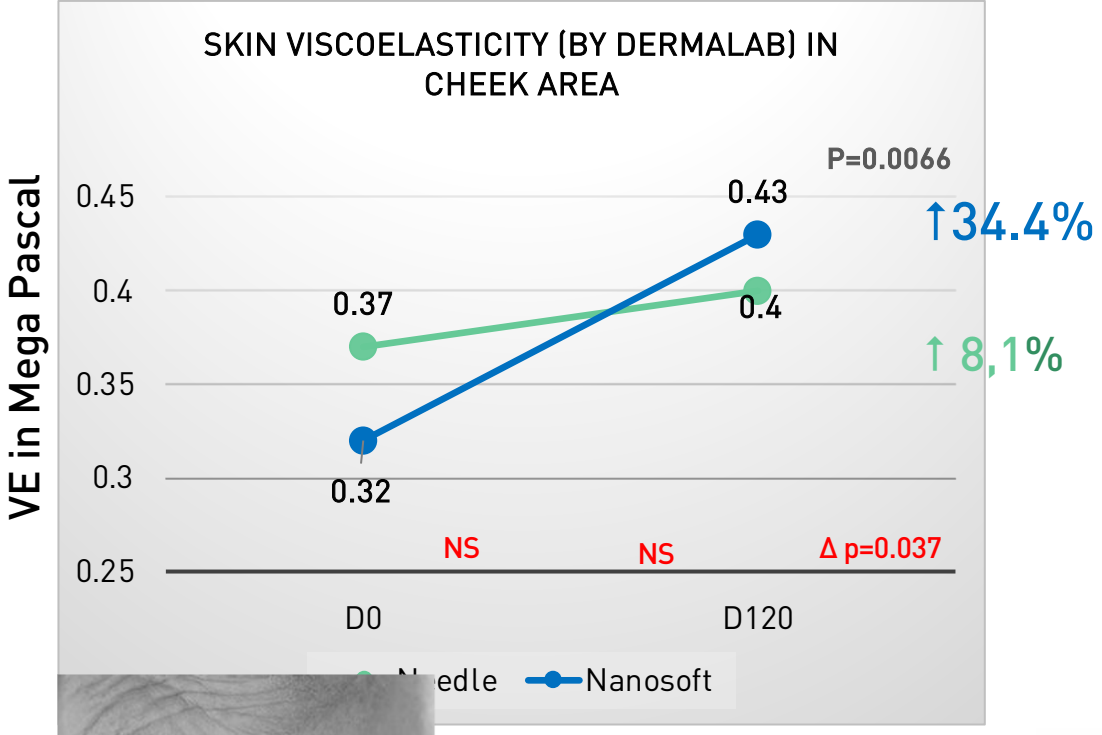
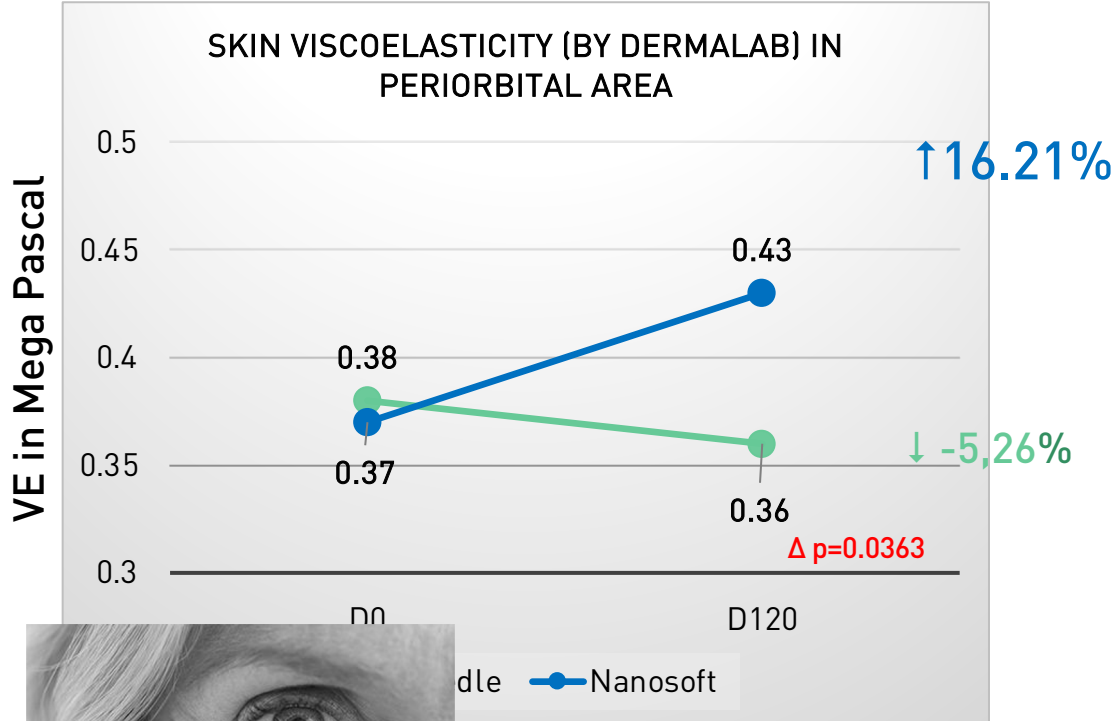
LEMPERLE SCORE

Wrinkles score diminished around **-40% for NANOSOFT®** side while it was diminished by around **-25% on 32G needle** side. Do not forget the role NCTF135HA® on both sides!



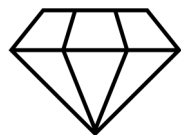
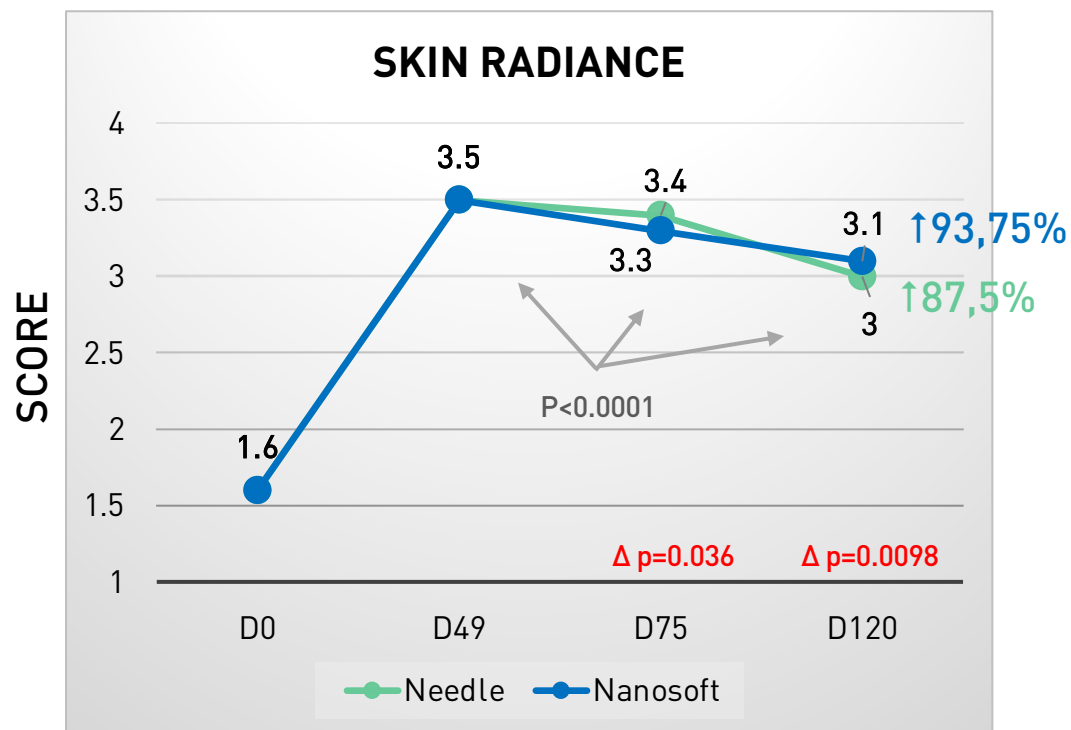
FACE: SKIN ELASTICITY (BY DERMALAB) VISCOELASTICITY 40 subjects

A significant difference of improvement in skin viscoelasticity was observed between D0 and D120 between two different side of the face for both periorbital area and cheeks ($\Delta p=0,0363$) in favor of Nanosoft®

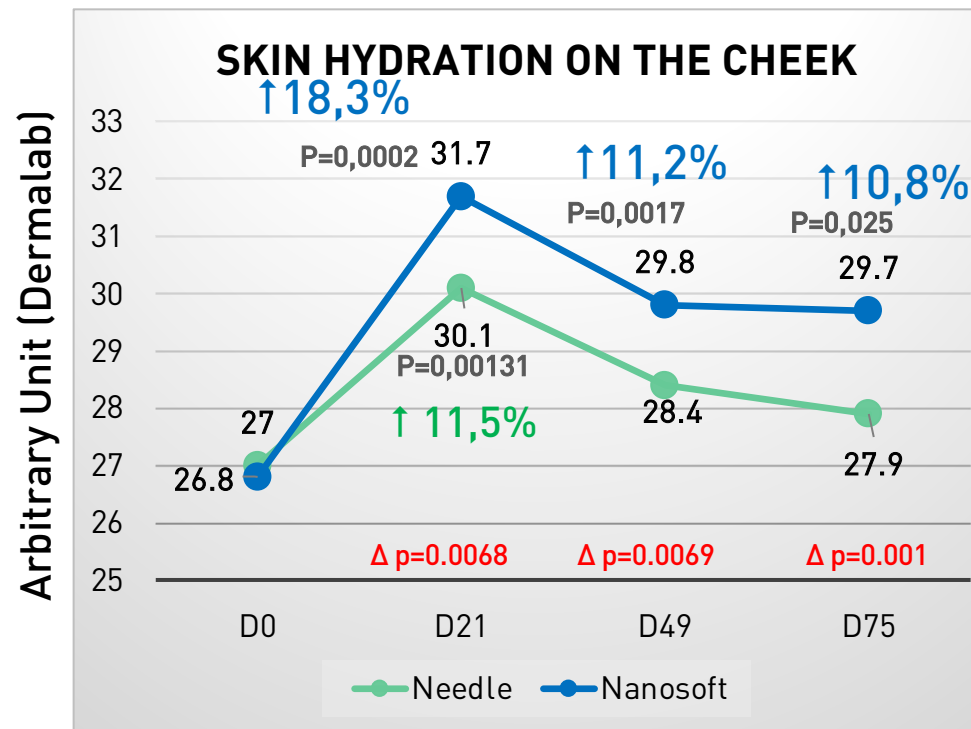


SKIN RADIANCE AND HYDRATION

Skin radiance increased significantly by both devices: **+93,75%** for NANOSOFT® side and **+87,5%** for classic needle side. These significant results are more understandable by the direct effect of NCTF135HA® than the injector effect.



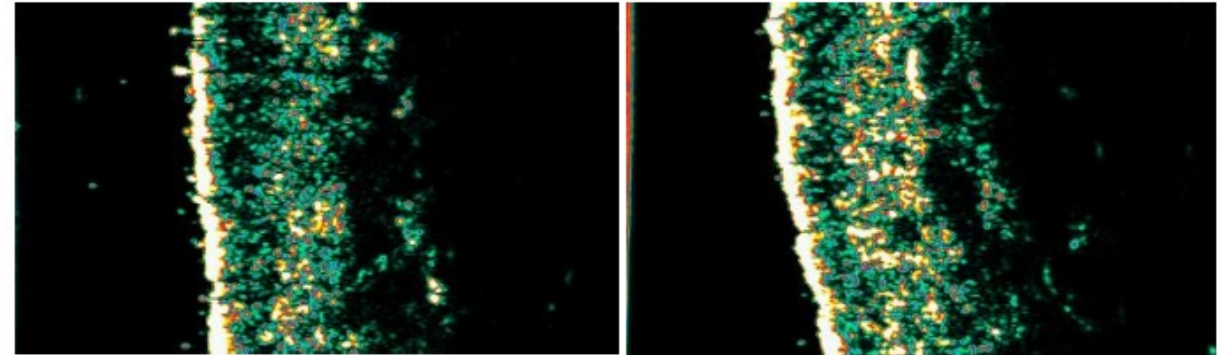
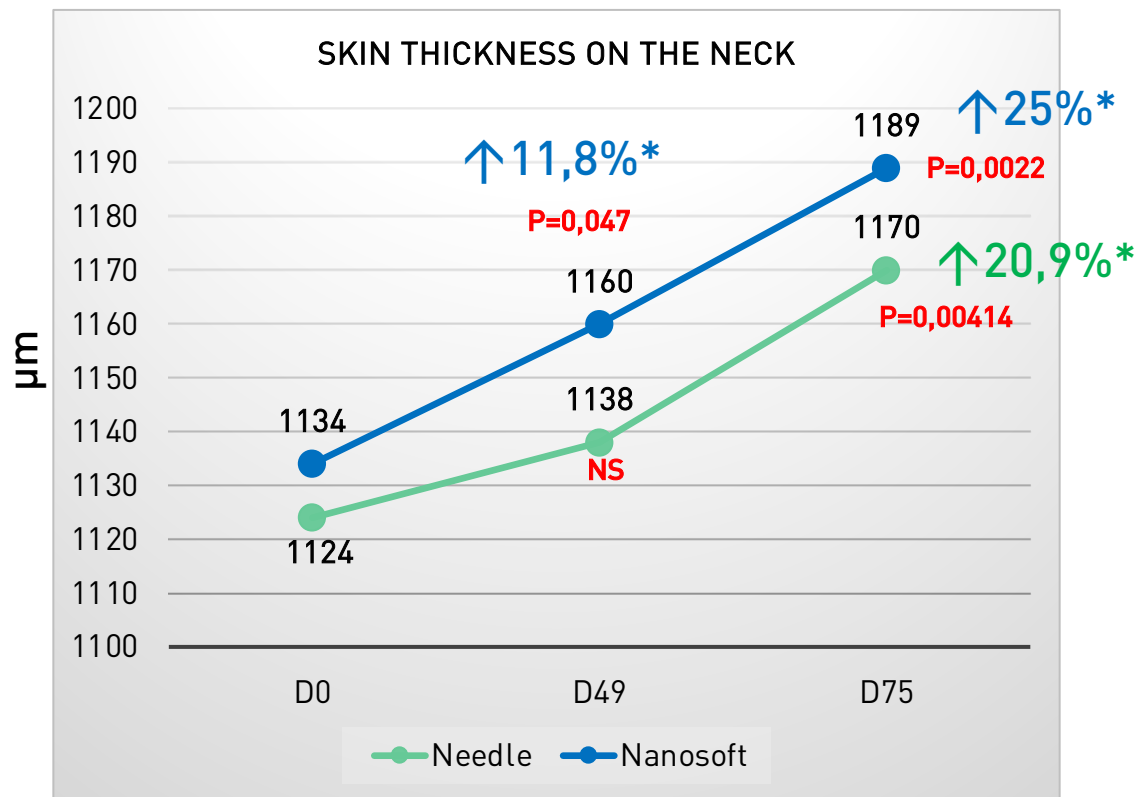
A significant improvement of skin hydration assessed by Dermalab® was observed with both injection methods after only one injection session which was statistically more significant for Nanosoft® side ($p=0.0068$). This difference remained significant till one month after the last injection (D75).



NECK: DERMAL THICKNESS

HIGH FREQUENCY ULTRASOUND IMAGING

40 subjects



A **significant increase** of neck skin thickness was observed as soon as one week after the last injection session only for Nanosoft® microneedle side ($p=0,047$). One month after the last injection session, the skin thickness increased significantly for both Nanosoft® and classic needle. It shows that the tissue remodeling by NCTF135HA® is more rapid with Nanosoft® than classic needle.

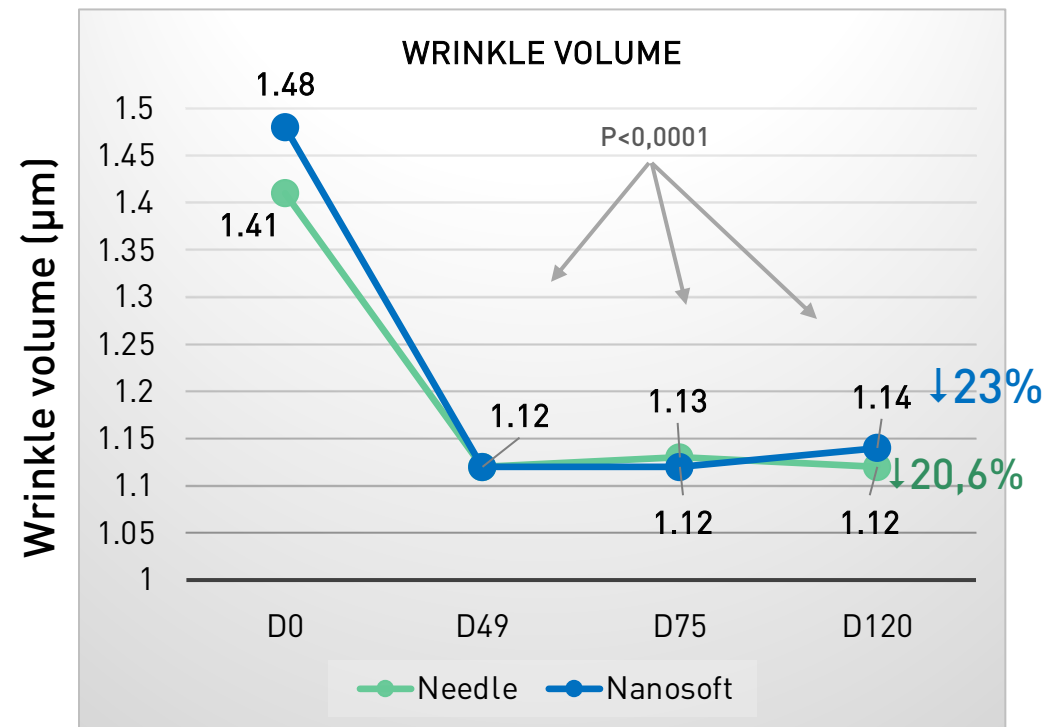
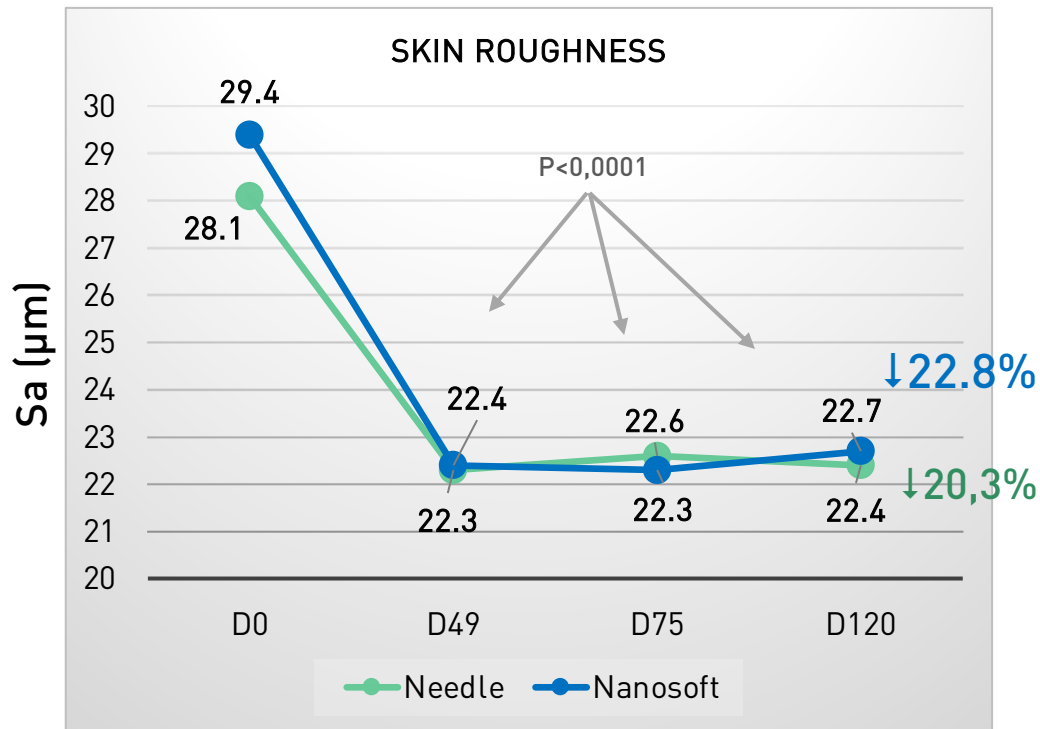


*Percentages calculated according the range of normal values of female and male of all ages ($\pm 220 \mu\text{m}$); Sanjana Iyengar et al., 2018



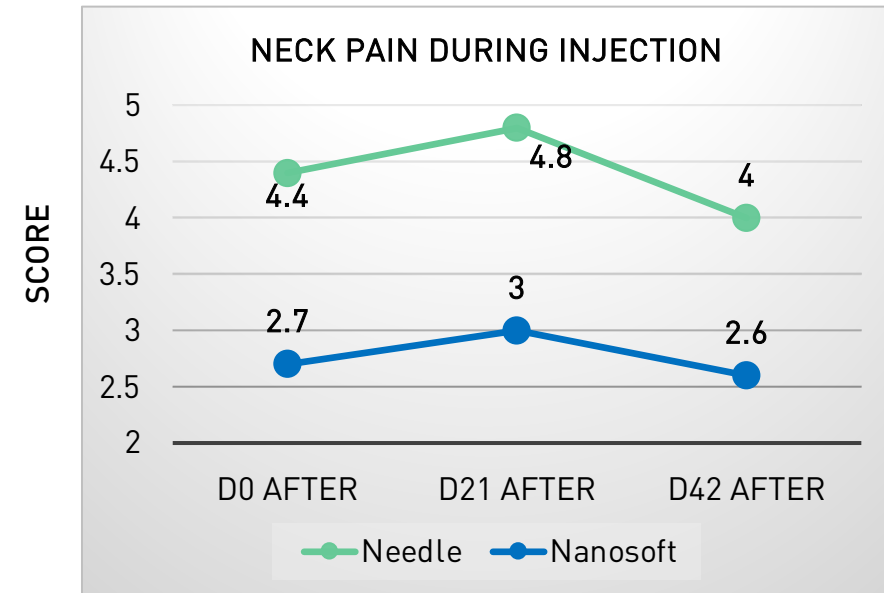
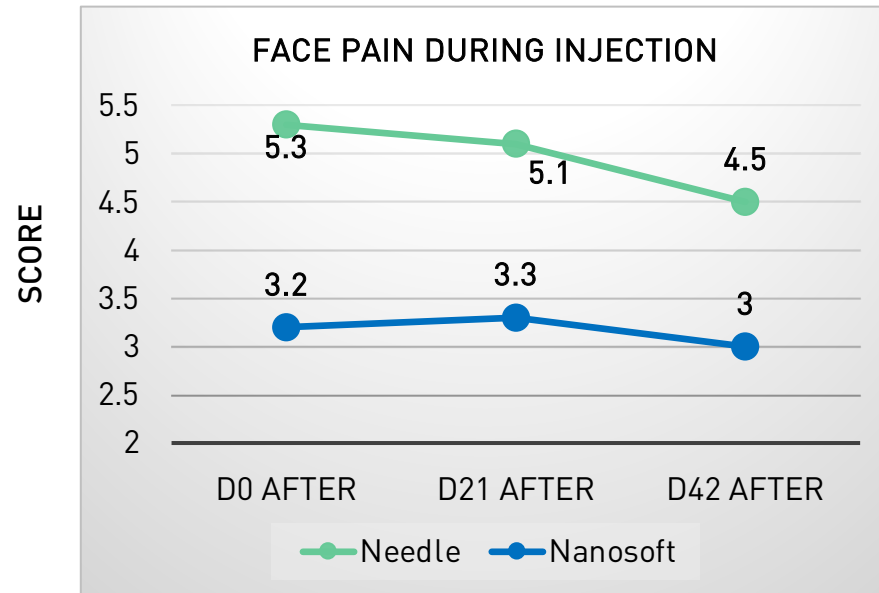
SKIN ROUGHNESS & WRINKLE VOLUME

Skin roughness and wrinkles volume were decreased significantly with both devices because these results are more dedicated to the role of NCTF135HA[®] than the injector itself.



PAIN SCORE

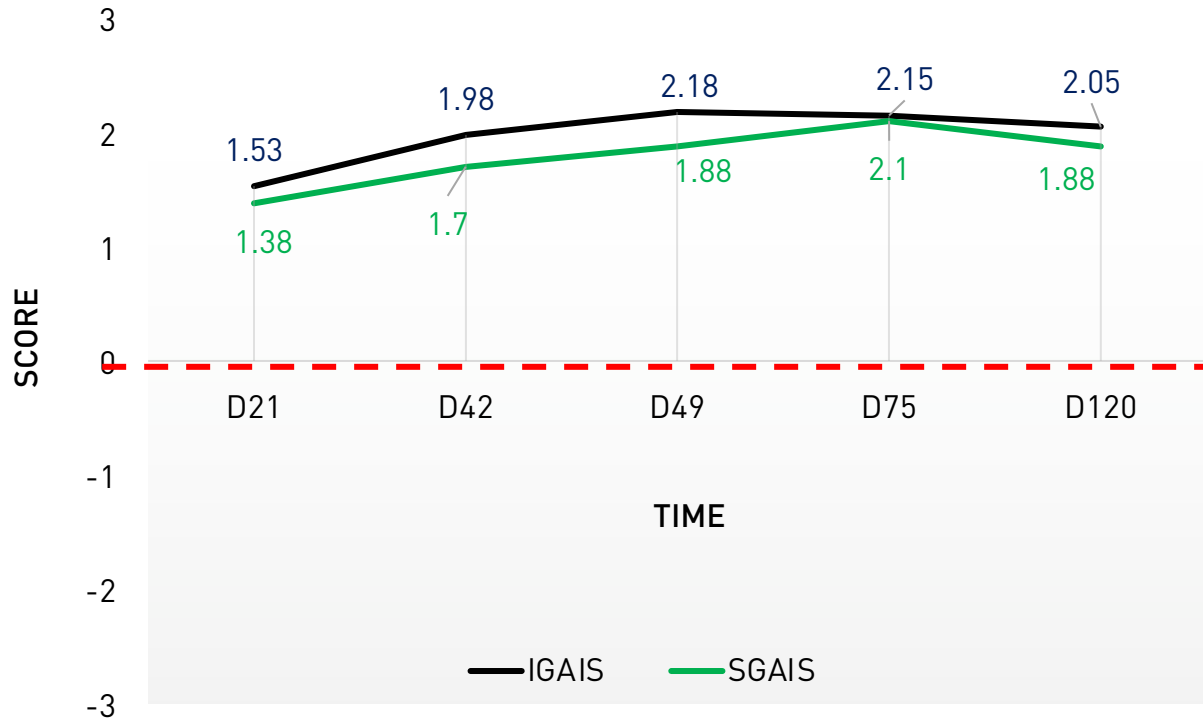
There is a significant difference of the pain sensation of the subjects during the injection for all sessions between the Nanosoft® side and classic needle side. The mean score for face is **4.96** for needle side versus **3.16** for Nanosoft® side on the scale of 0 to 10. The same difference is observable for neck (**4.4** for classic needle versus **2.7** for Nanosoft®)



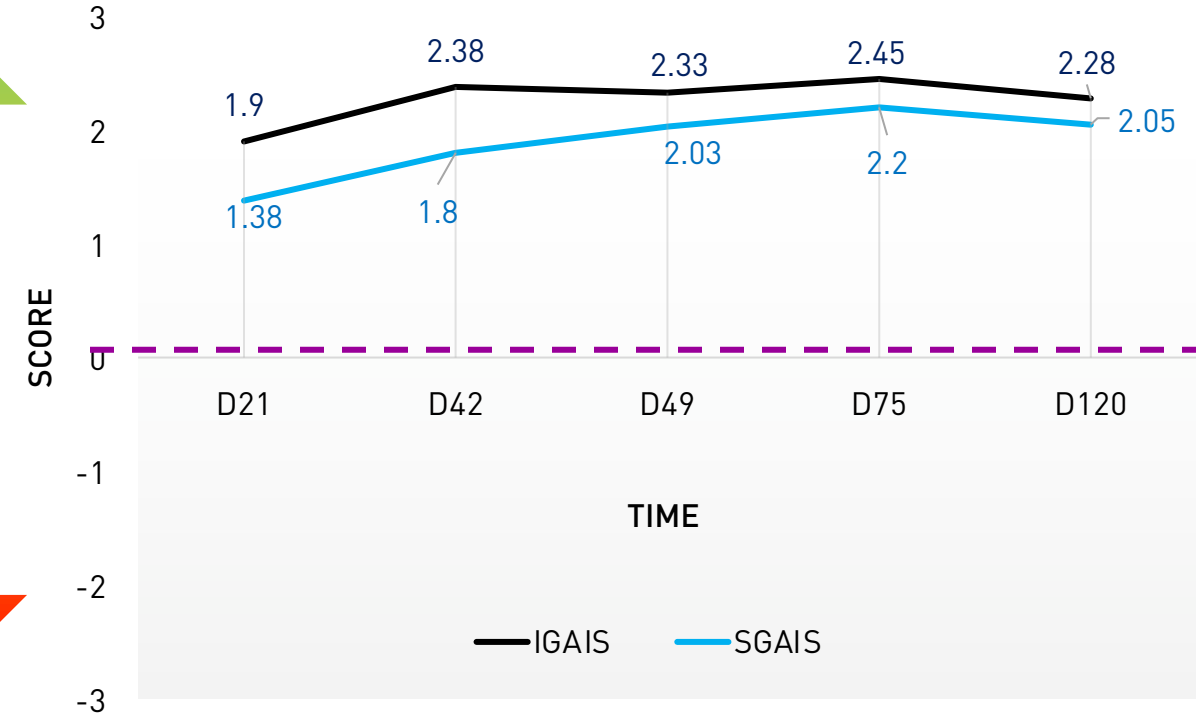
SUBJECT AND INVESTIGATORS SATISFACTION RATE FACE

For face, the mean satisfaction rate of the investigators for all time points (D21 → D120) is **2.26** for Nanosoft® while it is **1.97** for classic needle. This satisfaction is also superior for the Nanosoft® according to the subjects (**1.89** for Nanosoft® versus **1.7** for classic needle)

SATISFACTION RATE FOR CLASSIC NEEDLE



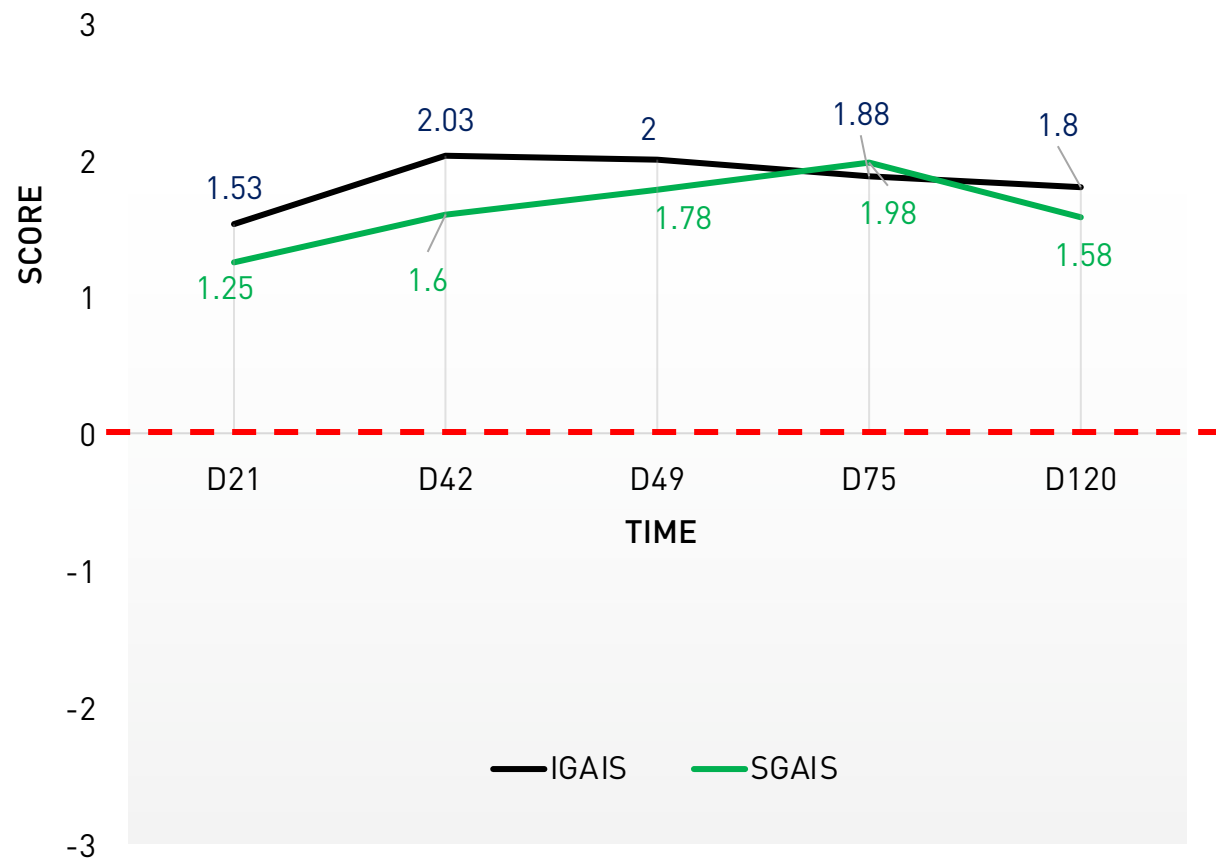
SATISFACTION RATE FOR NANOSOFT



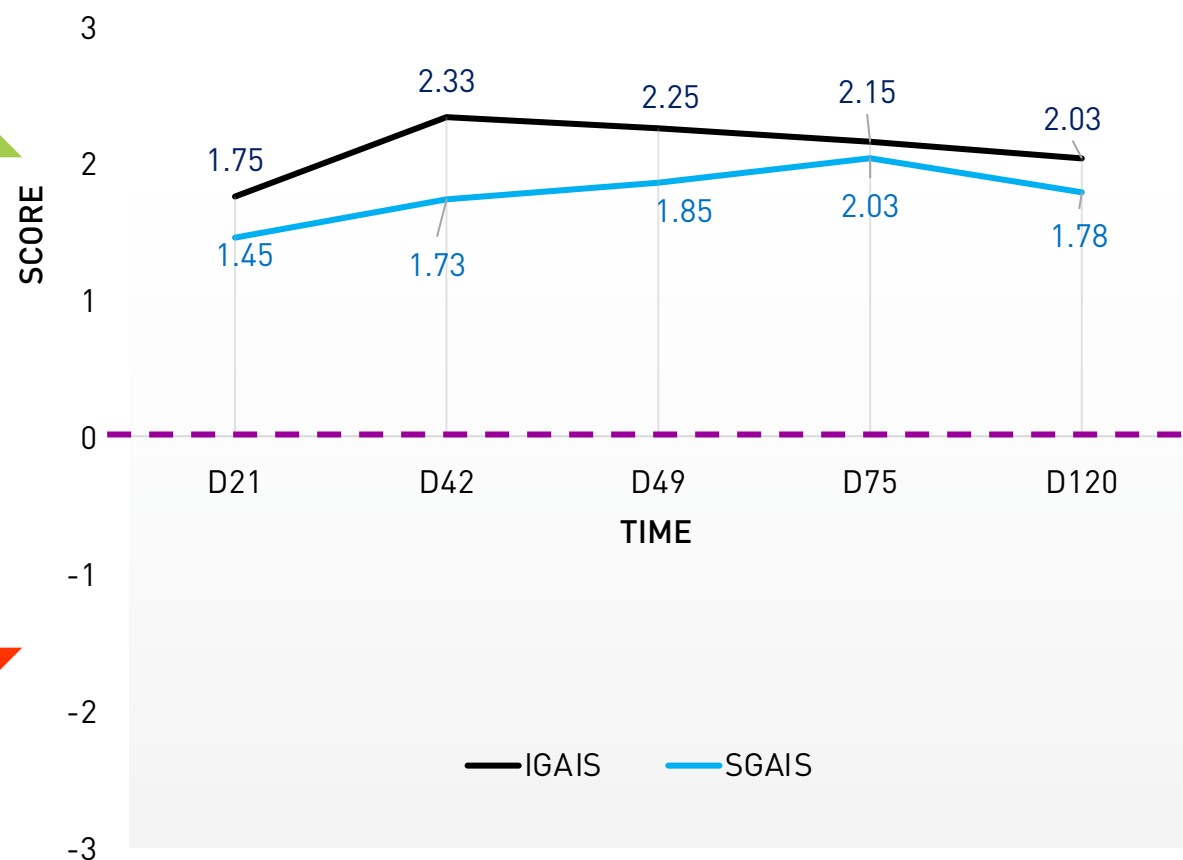
SUBJECT AND INVESTIGATORS SATISFACTION RATE NECK

For neck, the mean satisfaction rate of the investigators for all time points (D21→ D120) is **2.10** for Nanosoft® while it is **1.83** for classic needle. This satisfaction is also superior for the Nanosoft® according to the subjects (**1.76** for Nanosoft® versus **1.63** for classic needle)

SATISFACTION RATE FOR CLASSIC NEEDLE

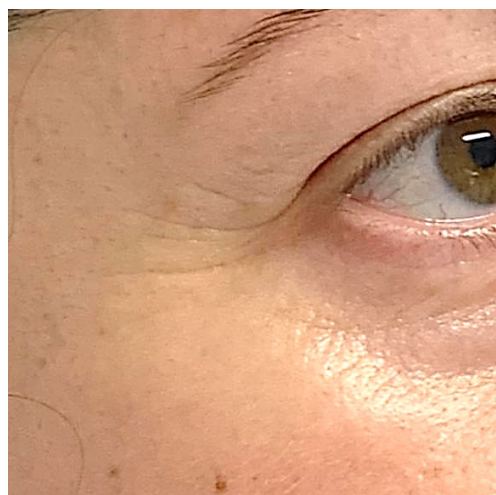


SATISFACTION RATE FOR NANOSOFT



BEFORE-AFTER PHOTOS

The improvement is more visible on Nanosoft® side.



D0



D120

Nanosoft®



D0



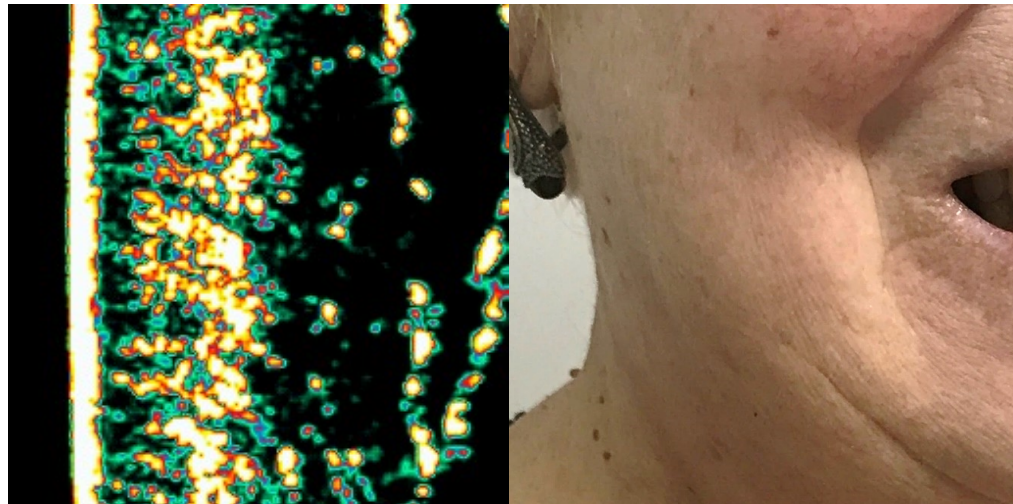
D120

Classic
Needle

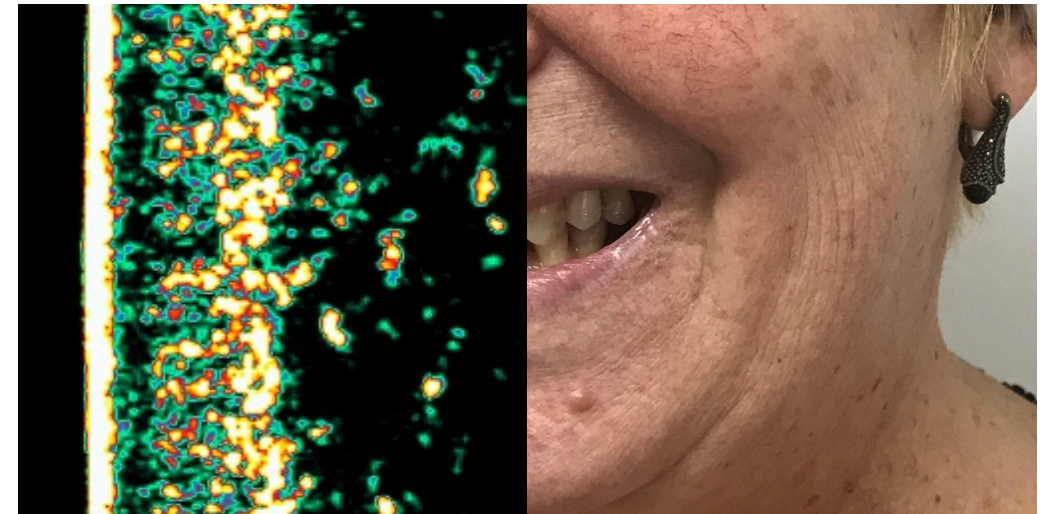
BEFORE-AFTER PHOTOS

The skin roughness is visibly lower on Nanosoft® side.

The skin thickness and density is higher in Nanosoft® side (yellow points are indicators of neocollagenesis)



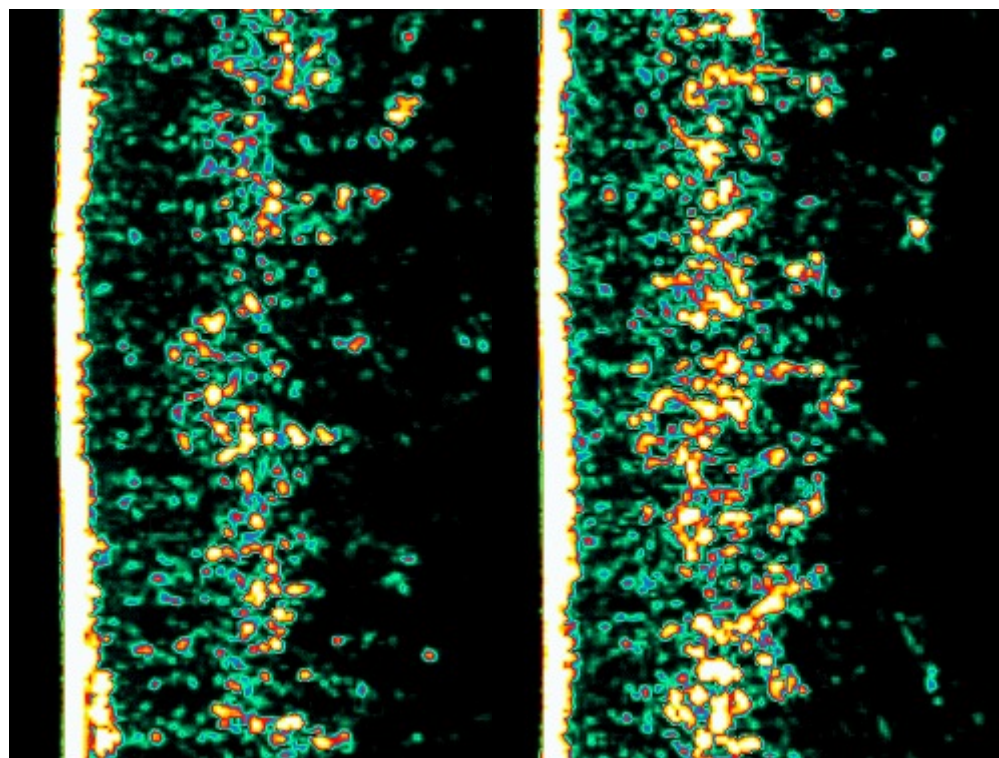
D120
Nanosoft®



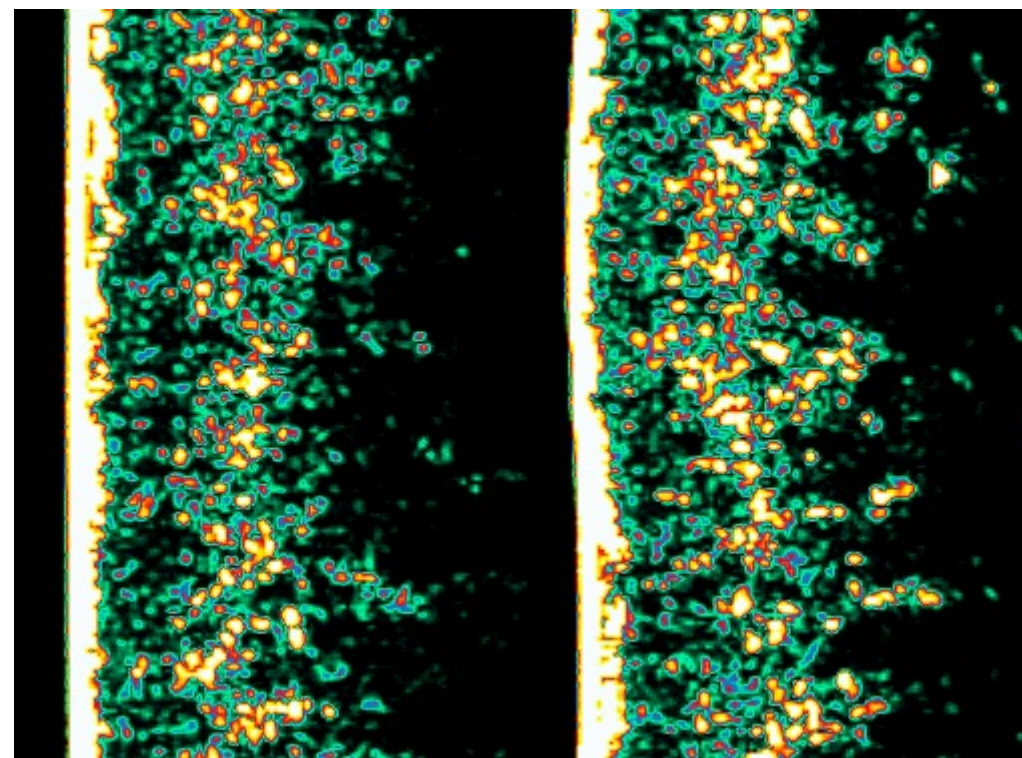
D120
Classic
Needle

HF ULTRASOUND IMAGING

The tissue induction is observed at both side but the evolution is more visible at Nanosoft® side



D120
Nanosoft®



D120
Classic
Needle

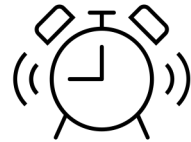


CONCLUSION

Interest of NCTF135HA® with NANOSOFT

➤ NCTF 135 HA improves the skin quality with both injector devices but NANOSOFT® provides:

➤ MORE RAPID RESULTS



➤ MORE EFFICIENT RESULTS



➤ LONGER RESULTS



➤ ALMOST PAINLESS TREATMENT, LESS BRUISE



➤ QUICKER & REPRODUCIBLE PROCEDURE





DEDICATED PROTOCOLS WITH NANOSOFT™



FORMULATION NCTF® 135 HA



FREE HMW HYALURONIC ACID 5mg/ml + ESSENTIAL INGREDIENTS *

- **24 Amino Acids**

Acide α -amino-butyrrique, Alanine, Arginine, Asparagine, Acide Aspartique, Cystine, Glutamine, Acide Glutamique, Glycine, Histidine, Hydroxyproline, Isoleucine, Leucine, Lysine, Methionine, Ornithine, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophane, Tyrosine, Valine

- **12 Vitamins**

Acide Ascorbique (Vit. C), Biotine (Vit. B8), Acide Pantothenique (Vit. B5), Acide Folique (Vit. B9), Inositol (Vit. I), Nicotinamide (Vit. B3), Pyridoxine (Vit. B6), Riboflavine (Vit. B2), Thiamine (Vit. B1), Tocopherol (Vit. E), Retinol (Vit. A), Vitamine B12

- **6 Minerals**

Calcium chloride, Potassium chloride, Magnesium sulfate, Sodium acetate, Sodium chloride, Sodium dihydrogenophosphate

- **6 Coenzymes**

- **5 Nucleic Acids (DNA reparation)**

- **1 Reducing agent (Glutathion)**



**A COMPLETE COCKTAIL
FOR BIOREVITALIZATION**





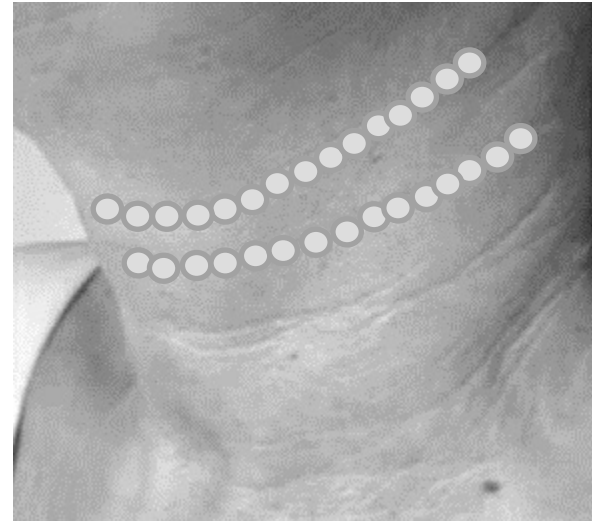
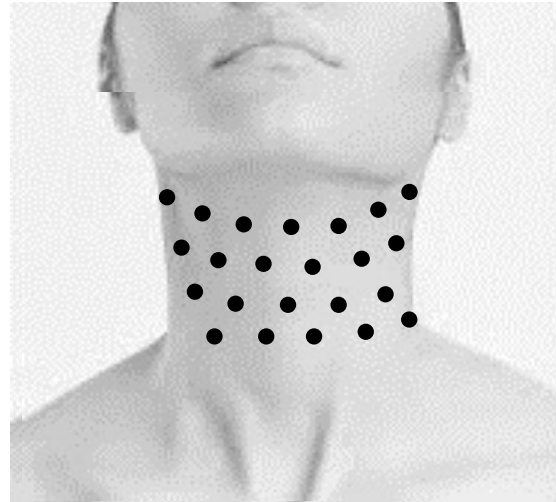
BIONUTRINECK

PEELING & M-HA 10 & NCTF



BIONUTRINECK PROTOCOL

A CUSTOMISED APPROACH



OBJECTIVE

REVITALISATION

REJUVENATION
CORRECTION

TARGET

>25 years old
No visible signs

> established signs
Necklines- Loss of firmness- Elastosis-Pigmentation

INJECTION

Every 1 cm to 1.5 cm

Point to point, alongside the wrinkles

BENEFITS

Skin quality- Hydration

Wrinkles- Homogeneity- Density



PROTOCOL OF 3 SESSIONS, 1½ MONTH

DAY 1

DAY 22

DAY 43

3 weeks

3 weeks



BIONUTRINECK PROTOCOL NCTF& NANOSOFT™





BEAUTIFEYE PROTOCOL

IT'S NOT WHAT YOU LOOK AT, BUT WHAT YOU SEE



TREATMENT OBJECTIVES

WRINKLES



- Skin tightening
- ↑ collagen & elastin

PIGMENTATION



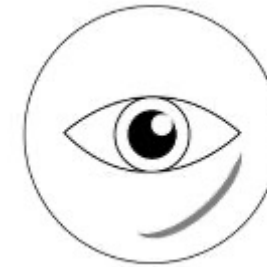
- Reduce pigmentation
- Improve skin quality
- Reduce inflammation

VASCULAR



- Reduce vascularity

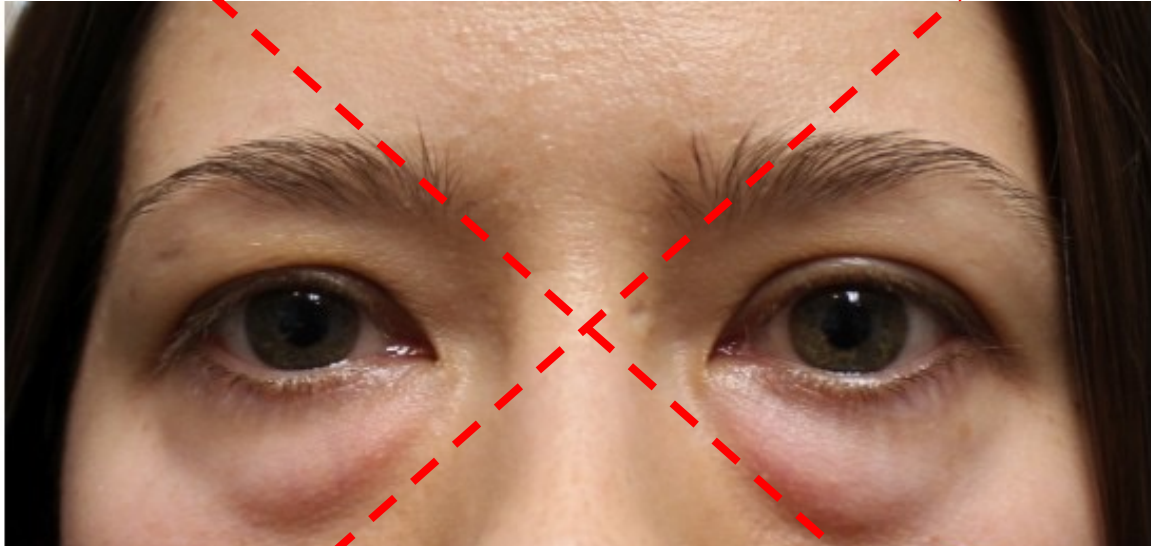
STRUCTURE



- Replace volume in appropriate parts
- Repair structural problems



PATIENT SELECTION: NO EYE BAG!



PROTOCOL OF 3 SESSIONS, 1 MONTH

DAY 1



DAY 15



DAY 30



NCTF® 135 HA cannot be injected on any disruption of skin barrier of the treated area.
A full recovery of the skin is necessary before injecting NCTF® 135 HA.



NANOSOFT® - IDEAL FOR THE EYE CONTOUR



> 3 microneedles, 0.6mm in length,
equivalent to 36G each

- Safer, less bruising
- Near painless
- Quicker results
- Standardised injection at the right depth delivering the right quantity of product
- Papulas disappear within 1- 24h max



PATIENTS BENEFITS

Fine lines, homogeneity, density, improved skin quality



VISIBLE RESULT EVENT AFTER 1 SESSION INTRADERMAL INJECTION OF NCTF®



1 month after only 1 session



VISIBLE RESULT INTRADERMAL INJECTION OF NCTF®



DR SERGIO FERNANDEZ



After 4 sessions



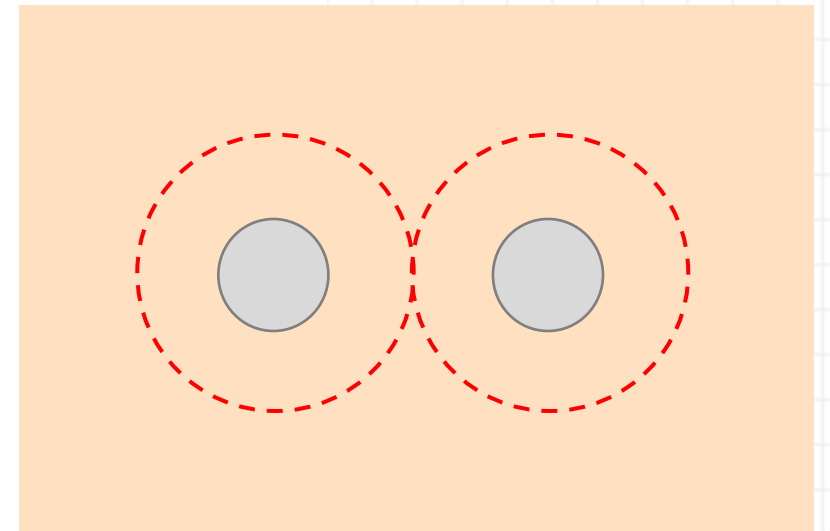


SAFETY TIPS WITH NANOSOFT™

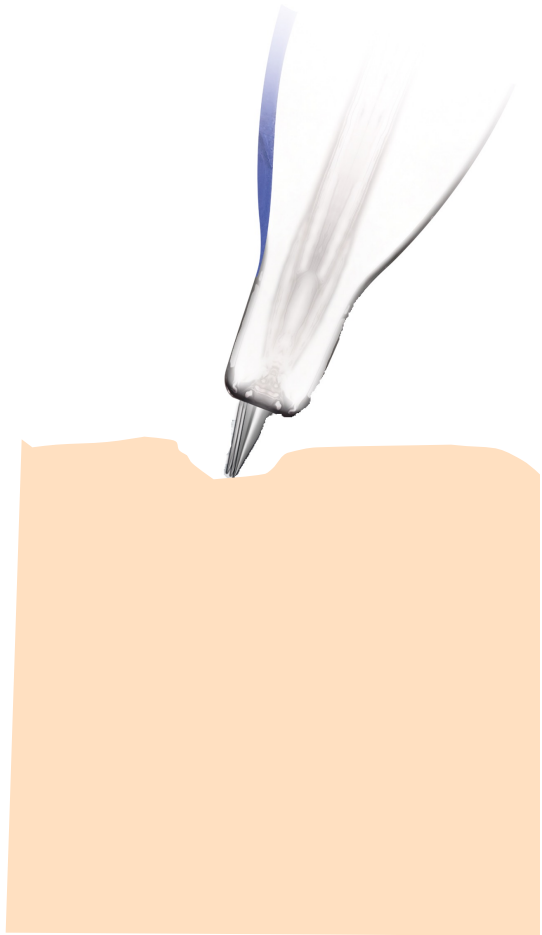


SAFETY TIPS

1. Patient Selection!
2. No Make UP!
3. Disinfection all face and NOT ONLY THE ZONE!!!
4. Minimum of pressure/trauma specially for periorbital area
5. As the skin reservoir is released 1 cm around the injection point, space 1 cm
6. For beginners with Nanosoft → Start on neck!
7. Each vial is for only one session/patient
8. NCTF is a good cell medium culture so is a good atmosphere for bacterial colonisation
9. If you use a device (needle pen or gun), you have to change the tip, you must not use the same tip for different patients!



MINIMUM OF TRAUMA INTO THE TISSU!



SAFETY TIPS

- **DOUBLE CHECK CONTRINDICATIONS:**

- PREGNANCY
- BREAST FEEDING
- AUTOIMMUNE DISEASE
- ALLERGY

- **PREPARE THE SKIN:**

- USE GLOVES
- MAKE UP REMOVAL (NO FOUNDATION 12 HOURS AFTER)
- PERFECT DESINFECTION OF ALL FACE!
- PATIENT MUST AVOID ANY EXPOSURE TO SUN AND EXTREME TEMPERATURES (SAUNA, COLD) FOR 48h AFTER THE INJECTION



SAFETY TIPS



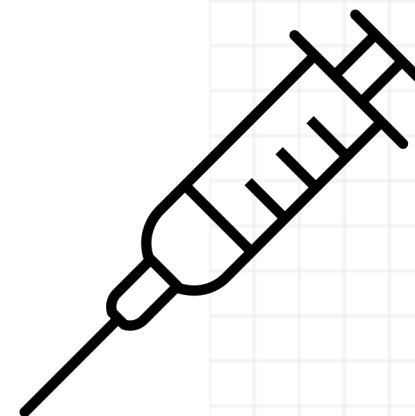
Each vial

=



1 patient

=

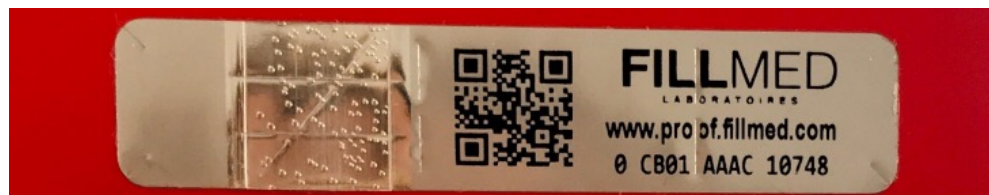


1 session



SAFETY TIPS

- **NCTF VIAL IS STERILE!**
 - EACH VIAL SHOULD BE USED ENTIRELY IMMEDIATELY AFTER OPENING
 - DO NOT REUSE 1 OPEN VIAL NEITHER FOR THE SAME PATIENT NEITHER FOR ANOTHER PATIENT
 - STORE BETWEEN 2C° AND 25C° MAX, AVOID SUN EXPOSURE
 - VERIFY THE ORIGINALITY OF THE PRODUCT THANKS TO THE PROOFTAG



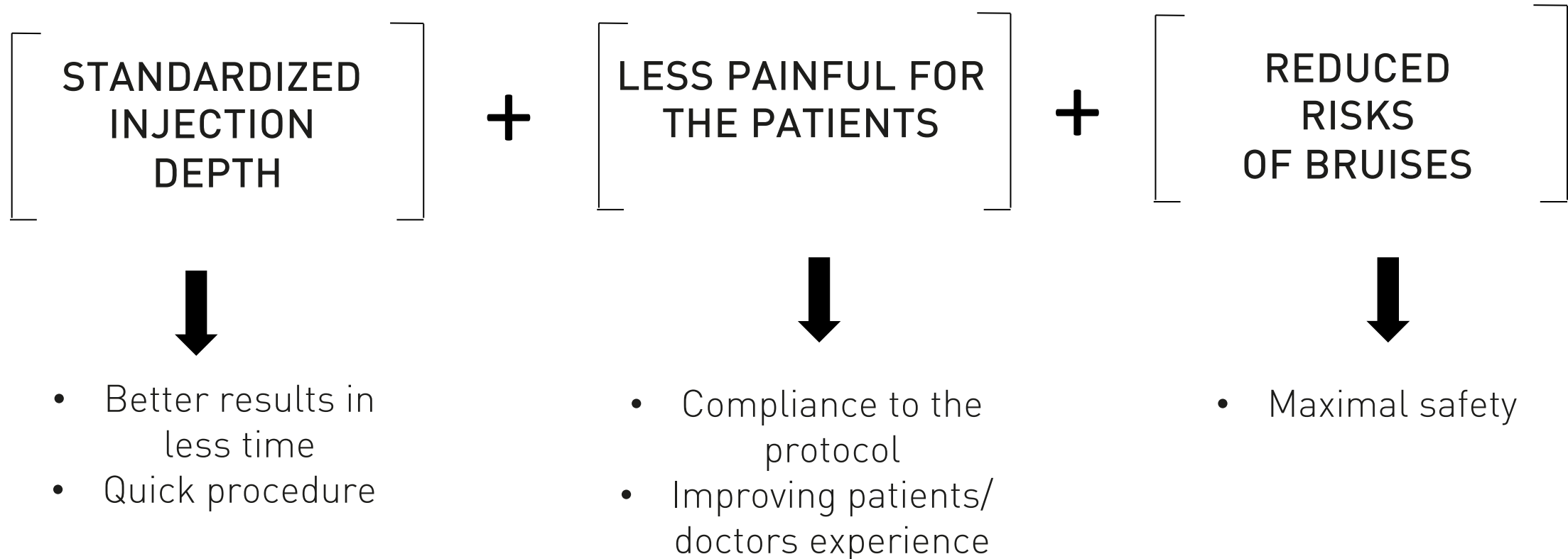


KEY SELLING POINTS



KEY SELLING POINTS WHEN THE DOCTOR MASTERS THE TECHNIC

THE SMALEST & THE SMARTEST



Q & A





BEAUTY IS AN ART, WE MADE IT A SCIENCE

NCTF INDICATIONS

NCTF 135 HA CONTRAINDICATIONS

Do not inject into blood vessels./ Do not use in: • patients with a skin alteration or disease of any kind in the treated area. • patients with a history of auto-immune disease or under immunotherapy. • patients with hypersensitivity or a known allergy to any of the constituents. • pregnant or breast-feeding women. • children.

NCTF®135 and NCTF®135 HA are injectable medical devices. For safety information, please refer to the Instructions for Use of each product. Vigilance contact (notification of an adverse event): vigilance@fillmed.com

Nanosoft™ is a medical device designed for intradermal injections by microneedles. For safety information, please refer to the Instructions for Use of the product. Vigilance contact (notification of an adverse event): vigilance@fillmed.com