

CE 1434
MEDICAL DEVICE CLASS III

NEXT GENERATION PLLA & PDLLA FILLER

PROLUMA PDLLA | PDLLA STRENGTH 200 MG

PROLUMA PLLA | PLLA STRENGTH 365 MG

That enhances skin rejuvenation and stimulates collagen using the distinct technology developed by Genèse Labs France

proluma.TM
Next Generation Facial Wrinkle Filler



GENÈSE LABS
PARIS





I ABOUT GENÈSE LABS

Based in Paris, France, Genèse Labs specializes in the development and marketing of a prestigious portfolio of aesthetic brands and products. Our extensive range includes facial injectables, collagen stimulators, body contouring solutions, skincare products, and much more.

At Genèse Labs, we are driven by the belief that confidence can transform the personal, professional, and business lives of our clients. This belief lies at the heart of our commitment to providing exceptional aesthetic solutions.

Our guiding philosophy at Genèse Labs is both simple and profound.

"We view beauty as an art form that requires the finest tools and a deep passion."

This philosophy shapes our mission to create a world that resonates with the elegance and charm inherent in French aestheticism.

| DISCOVER PROLUMA

ADVANCED COLLAGEN BIOSTIMULATION WITH PDLLA & PLLA

Proluma is a new-generation injectable collagen stimulator designed to restore facial volume and improve skin quality through natural collagen regeneration. It is available in two targeted formulations.

- **Proluma PDLLA (200mg)** – for smooth, balanced correction with uniform collagen stimulation
- **Proluma PLLA (365mg)** – for deep, long-lasting volumization and structural enhancement

Unlike HA fillers that provide immediate but temporary results, Proluma works beneath the surface to activate the body's own collagen production. This regenerative process leads to gradual, natural-looking improvements in skin texture, elasticity, and volume.

Proluma offers a personalized approach to facial rejuvenation
— built on science, safety, and subtle, lasting results.

| ABOUT PROLUMA



DEVELOPED BY GENÈSE LABS FRANCE

Backed by European expertise in regenerative aesthetics.



CE CERTIFIED

Meets rigorous European standards for safety and proven collagen-stimulating efficacy.



FDA-RECOGNIZED

Contains PLA (PDLLA & PLLA), a biocompatible polymer classified and recognized by the U.S. FDA as a safe and effective material for medical devices.



KFDA REGISTERED

Approved by the Korean Ministry of Food and Drug Safety, ensuring excellence in quality and production standards.

COLLAGEN AND SKIN AGING

THE IMPACT OF AGING FACTORS

The aging process causes fundamental changes in the skin, soft tissue, and skeletal support structures of the human face. Dermal changes are due to intrinsic and extrinsic factors:

- Intrinsic factors refer to genetically determined hormonal and biochemical processes that cause irreversible degeneration of skin tissue.
- Extrinsic factors refer to environmental influences, particularly UV radiation, that damage the skin and compromise skin integrity.

AS AGING OCCURS

- The dermis thins owing to collagen loss¹
- Moisture retention is reduced owing to HA loss²
- Elasticity is reduced owing to loss of elastin³

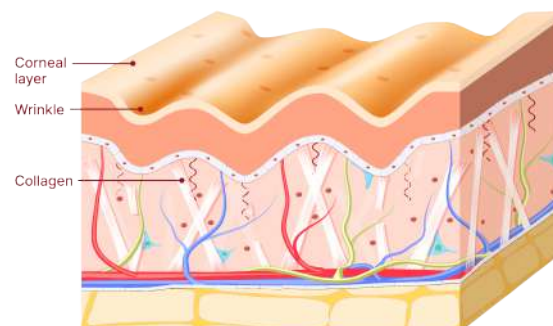
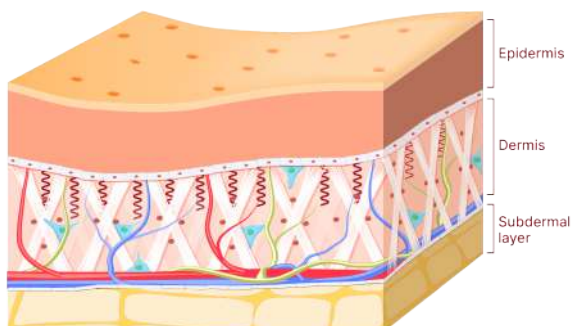


Young skin

- Thicker corneal layer
- Large number of cells
- Multiple crests and papillae
- Thicker subdermal layer
- High collagen deposit rates

Old skin

- Thin corneal layer
- Low number of cells
- No or few crests and papillae
- Thin subdermal layer
- Decrease in collagen turnover



1. UV, ultraviolet. Sadick NS, et al. Clinics Dermatol.2009;27:S3-S12.

2. HA, hyaluronic acid. : Vleggaar D and Fitzgerald R.J Drugs Dermatol. 2008;7:209;2. Papakonstantinou E, et al. Dermato-Endocrinology2012;4(3):253-258; 3. Farage MA, et al. Adv Wound Care.2007;2(1):5-10.

3. Farage MA, et al. Adv Wound Care. 2007;2(1):5-10.

WHAT IS COLLAGEN?

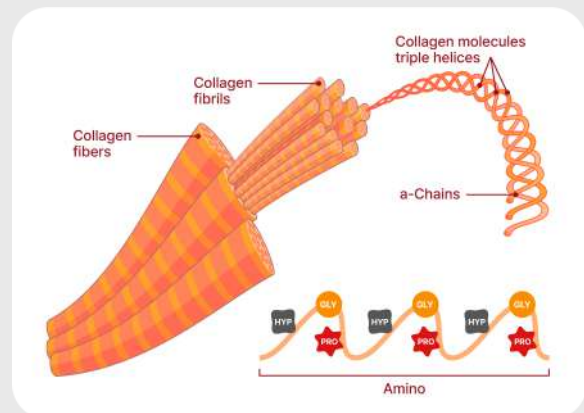
Collagen is the most abundant protein in your body. It corresponds to 95% of the connective tissue of the dermis and to 30% of the overall proteins of the body. Collagen is the primary building block of your body's skin, muscles, bones, tendons and ligaments, and other connective tissues. It's also found in your organs, blood vessels and intestinal lining.

WHAT DOES COLLAGEN DO?

Collagen's main role is to provide structure, strength and support throughout your body.

Collagen's specific roles include:

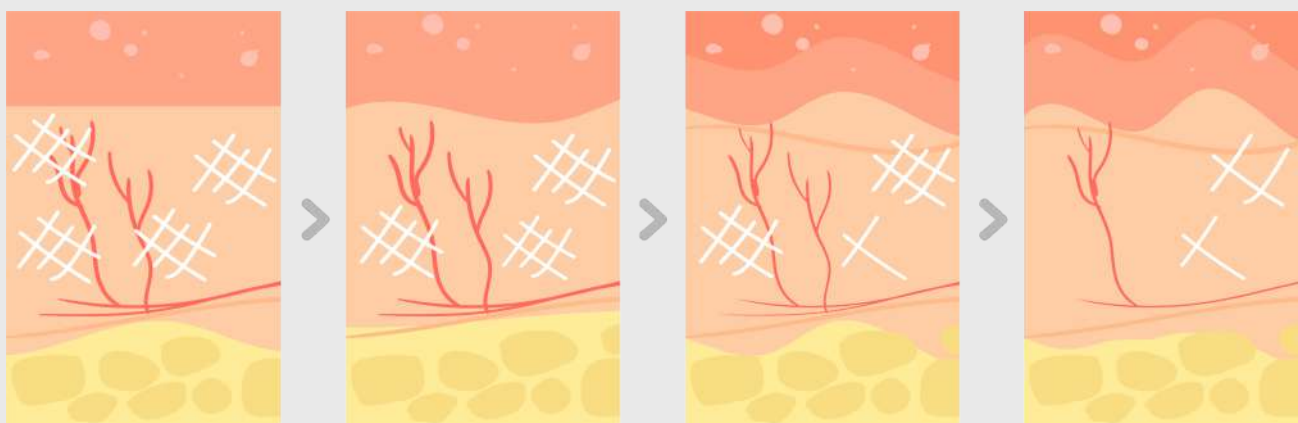
- Helping fibroblasts form in your dermis (middle skin layer), which helps new cells grow.
- Giving structure, strength and elasticity to your skin.
- Playing a role in replacing dead skin cells.
- Providing a protective covering for organs.
- Helping your blood to clot.



SKIN AGING STARTS TO SHOW AROUND AGE 30 AND WORSENS PROGRESSIVELY¹

The production of collagen decreases with age, as does the quality of the collagen produced; its degradation also increases with age owing to

- Fragmented collagen elastic fibers^{2,3}
- Collapse of fibroblasts
- Decreased collagen production⁴
- Increased matrix metalloproteinase production⁵
- Degradation of the extracellular matrix⁶



Shoulders M and Raines R. Annu Rev Biochem. 2009;78:929-958.

1. Ascher B, et al. Dermatol Surg. 2006;32:1058; 2. Ganjoo A. Aging skin. In: ACS(II) Textbook on Cutaneous & Aesthetic Surgery. 2012; 3. Donofrio LM. Dermatol Surg.2000;26:1107;

4. Vleggar D and Fitzgerald R. J Drugs Dermatol. 2008;7:209; 5. Helfrich YR, et al. Dermatol Nurs. 2008;20:177; 6. Zhang S, Duan E. Cell Transplantation.2018;27(5):729-738.

WHY PLA (PDLLA & PLLA)?

Polylactic Acid (PDLLA & PLLA), PDLLA(Poly D, L-lactic acid), PLLA(Poly L-lactic acid) is a premium, biodegradable polymer renowned for its application in the medical sector. Engineered for excellence, PLA (PDLLA & PLLA) serves as a cornerstone material in the production of an array of medical devices, including surgical sutures, orthopedic implants, and advanced drug delivery systems. This state-of-the-art polymer distinguishes itself through its controlled degradation into lactic acid, a substance naturally metabolized by the human body, ensuring minimal physiological impact.

A key feature of PLA (PDLLA & PLLA) is its role in stimulating collagen production, an essential process for tissue regeneration and healing.

Collagen Production	Tissue Regeneration	Fibroblast Activation
Stimulated by the presence of immune cells and the degradation products of PLA (PDLLA & PLLA), fibroblasts begin to produce and organize new collagen fibers. This collagen synthesis helps in tissue regeneration and the healing process, gradually replacing the PLA (PDLLA & PLLA) structure with natural tissue.	Over time, as PLA (PDLLA & PLLA) completely degrades and is replaced by newly formed tissue, the collagen structure becomes more organized, restoring the tissue's strength and functionality.	Among the immune cells attracted to the site are fibroblasts, which play a crucial role in wound healing and tissue regeneration. Fibroblasts are responsible for producing collagen, the primary structural protein in connective tissues.
This ability to stimulate collagen production and support tissue regeneration makes PLA (PDLLA & PLLA) particularly useful in applications requiring bioresorbable materials, such as in facial rejuvenation treatments, where it can help improve skin texture and volume by enhancing the body's natural collagen synthesis.		

PLA (PDLLA & PLLA) COMPARE OTHER TYPES OF INJECTIONS

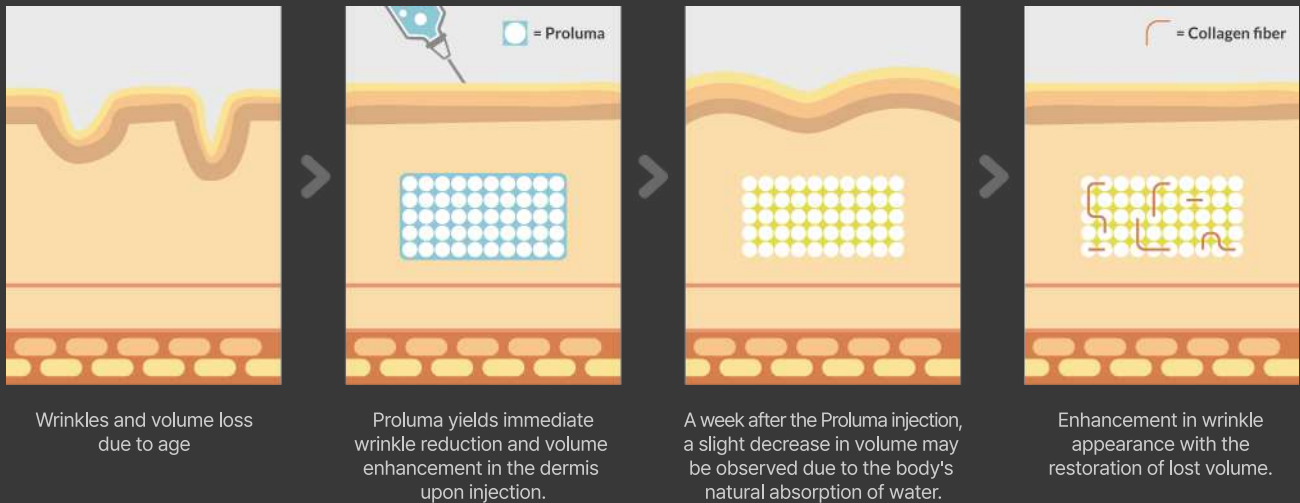
			
Botulinum Toxin	HA Fillers	Skin Boosters	PLA Fillers
Relax	Refine	Refresh	Renew

	Proluma	Traditional Fillers
MATERIAL	Polylatic Acid PLA (PDLLA & PLLA)	Hyaluronic Acid
HOW IT WORKS	Stimulation of collagen to increase volume	Volume gains from physical prosense of material injected
RESULTS	Seen over time	Immediate but depreciates over time
LAST THROUGH	About 1-2 years	About 6-9 months
BENEFITS	- Does not migrate - Does not attracts water - More natural looking - Little risk of intra-vascular occlusion	- Possible migration - Potentially attracts water and swells - Less natural looking - Higher risk of intra-vascular occlusion - Exercise/heat/massage may affect post treatment result

MECHANISM OF PROLUMA™

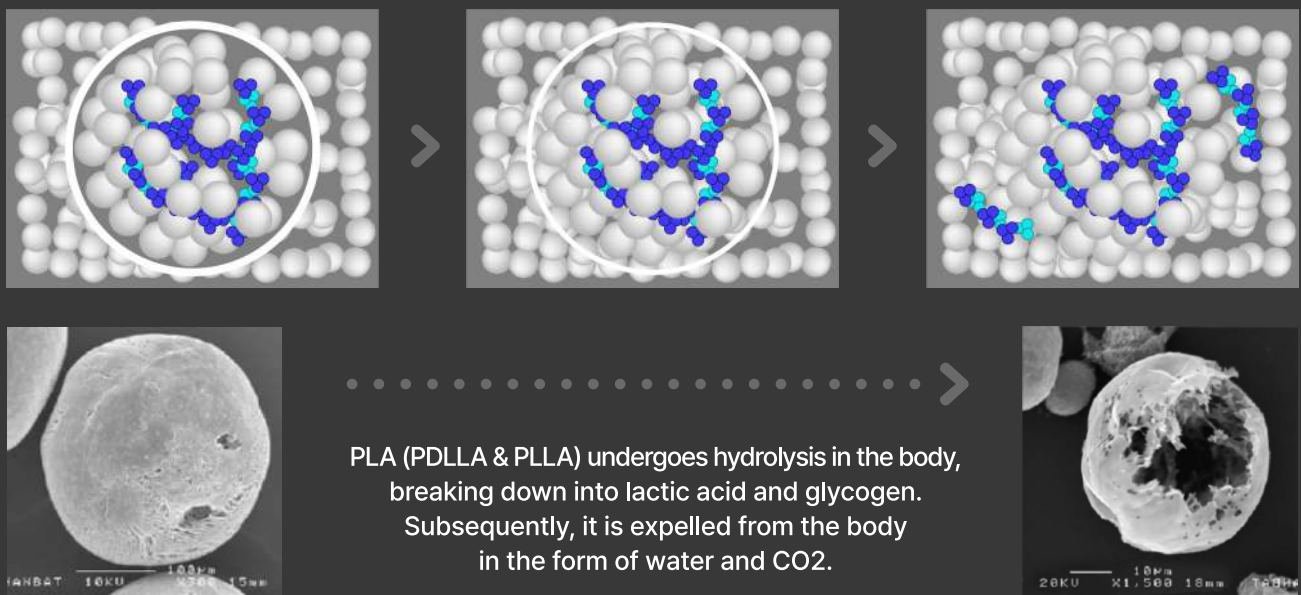
As we age, there's a decrease in collagen, water, and other vital tissues. PLA (PDLLA & PLLA) fillers are utilized to add volume to the face and to encourage the production of collagen and additional tissues.

The injection delivers an immediate volume-enhancing effect, noticeable directly following the injection, showcasing an instant augmentation in the treated area.



Between weeks 1 and 2 post-injection, a temporary volume reduction may be noticed. However, from weeks 4 to 8, the stimulation of cellular activity and collagen synthesis begins to replenish the lost volume. The gradual formation of collagen over time is facilitated by cells migrating into the porous PLA (PDLLA & PLLA) particles, ensuring a sustained volumizing effect.

The scaffolds, comprised of PLA (PDLLA & PLLA) particles, are eventually absorbed and replaced by cells and other biological materials within the structure, seamlessly integrating into the tissue.

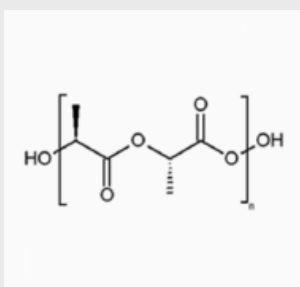




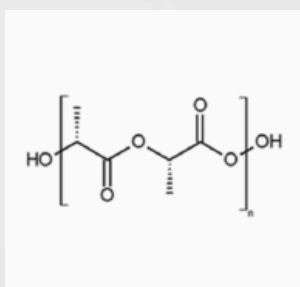
| PDLLA VS PLLA?

Injectable PLLA vs PDLLA: Composition and Collagen Formation

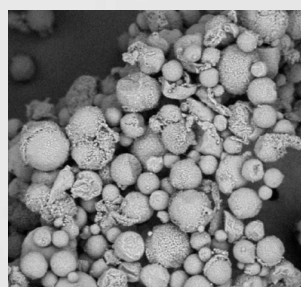
The Proluma PLA line-up consists of PDLLA and PLLA—two powerful forms of polylactic acid used in modern aesthetic medicine to stimulate collagen regeneration and restore youthful skin structure. With distinct molecular structures and clinical profiles, each offers unique advantages for addressing a broad spectrum of aging concerns. **Proluma PDLLA** and **Proluma PLLA** are advanced collagen biostimulators, carefully developed to meet the diverse needs of patients—whether for early intervention or long-lasting volumization. While both formulations trigger the skin's natural regenerative response, they are each optimized for different treatment depths, aesthetic indications, and patient demographics. The comparison below outlines their key differences, empowering practitioners to tailor treatment strategies with precision and confidence.



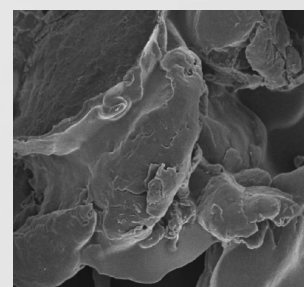
PDLLA



PLLA



PDLLA
Microspheres



PLLA
Microparticles



Proluma 200mg PDLLA



Proluma 365mg PLLA

MAIN INGREDIENT	Poly-D,L-lactic acid (PDLLA), CMC	Poly-L-lactic acid (PLLA), CMC & Mannitol
IDEAL PATIENT AGE	30s~40s+ (fast result)	40s~60s+ (advanced volume loss and facial sagging)
PRACTITIONER TARGET USE	Skin rejuvenation, touch-ups, combination protocols	Full facial volume restoration, contouring, long-term plans
RECOMMENDED INJECTOR LEVEL	General practitioners & experienced users	Mid-to-advanced level injectors preferred
PARTICLE STRUCTURE	Amorphous (lower crystallinity)	Crystalline (high crystallinity)
RECONSTITUTION TIME	Fast (1 hour)	Longer (2 hours)
INJECTION DEPTH	Superficial to mid-dermis	Deep dermis, subdermal, or periosteal
TREATMENT AREAS	Cheeks, temples, mid-face, neck, fine lines	Nasolabial folds, chin, jawline, full-face volume loss
ONSET OF RESULTS	3–4 weeks	6–8 weeks
VOLUMIZING EFFECT	Moderate	Strong and deep
LONGEVITY OF RESULTS	Up to 18–24 months	Up to 24+ months
BIOSTIMULATION PROFILE	Balanced collagen stimulation with smoother degradation	Deeper, prolonged collagen stimulation
HANDLING EASE	Smoother, low risk of clumping	Requires experienced handling and mixing
POST-TREATMENT DOWNTIME	Minimal (mild redness/swelling)	Slightly longer (may involve swelling/bruising)

WHY PROLUMA PDLLA?

Engineered with **distinctive polymer technology by Genèse Labs France**, Proluma PDLLA utilizes poly-D, L-lactic acid to deliver smooth, uniform collagen stimulation and controlled biodegradation. Its refined particle structure ensures balanced correction, making it ideal for patients seeking natural skin rejuvenation, improved texture, and subtle volume restoration. The result is a refreshed, youthful appearance with minimal downtime and visible improvements within weeks.



Preparation Time | Ready in approximately 30 minutes



Ideal Age Group | Patients in their 30s to 40s



Treatment Areas | Cheeks, temples, nasolabial folds, neck



Target Use | Skin rejuvenation, fine lines, subtle volume restoration



Recommended Injector Level | Suitable for general aesthetic practitioners and advanced users

PROLUMA SPECIFICATIONS

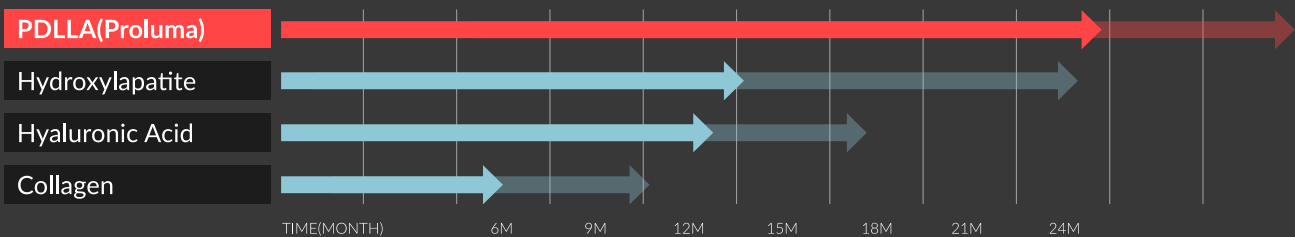
INGREDIENTS	PLA(Poly DL-Lactide)	INJECTION FORCE	3.5 N
MANUFACTURING METHOD	Freeze drying	HARMFUL RESIDUE	0.006 EU/mg
MOLECULAR WEIGHT	190,000-250,000 DA	COMPOSITION	PLA 77%, CMC 23%
CANNULA	25G	DISSOLUTION TIME	1 hour
MICROSPHERES	30-50 um		



EFFICIENCY OF PROLUMA PDLLA

1. FAST-ACTING COLLAGEN STIMULATION

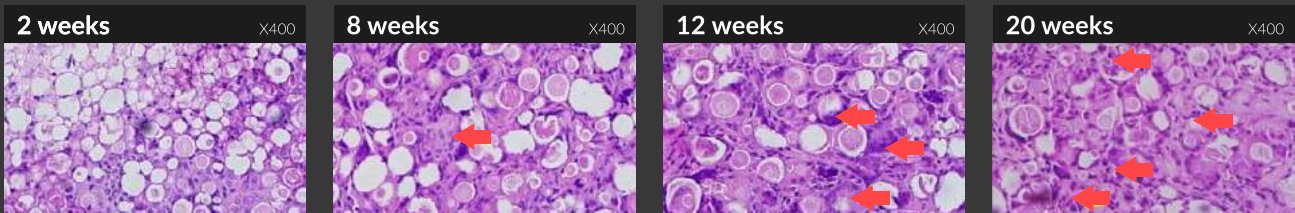
Proluma stands out by not only correcting wrinkles and folds but also ensuring lasting volumization across facial areas, offering a durable alternative to traditional fillers that target specific folds. Its effectiveness in enhancing natural facial volume through the stimulation of new collagen and tissue production contributes to its long-lasting results.



2. NEW TISSUES AND COLLAGEN PRODUCTION

Proluma effectively promotes the generation of new tissues and collagen, demonstrating a progressive cellular response to the treatment:

- By Week 2 post-injection, cellular proliferation is evident as cells begin to adhere to the surface of PDLLA particles and occupy the interstitial spaces between them, effectively filling these voids with new tissue growth.
- By Week 8, the previously observed spaces between PDLLA particles no longer exist, having been completely occupied by cells. These cells initiate migration into the porous structure of the PDLLA particles, as indicated by the yellow arrow.
- By Weeks 12 and 20, an advanced stage of cellular integration is observed. Cells have penetrated deeply into the inner regions of the PDLLA particles, thoroughly inhabiting both the internal spaces and the areas between particles, culminating in significant tissue regeneration and volumization.

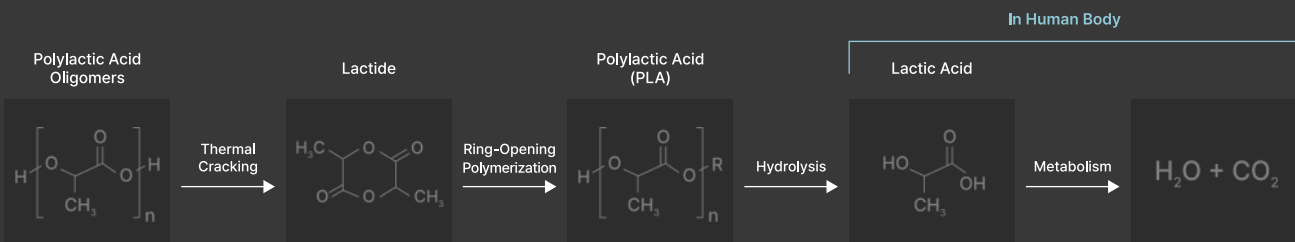


Pink(Cytoplasm): Dark pink or blue(Nucleus)
Arrows: Cells migrated into inside PDLLA particles

3. SAFETY : BIODEGRADABILITY

PDLLA, known for its safety and non-toxic properties, undergoes degradation in the body via hydrolysis, breaking down into lactic acid and glycogen. Through metabolic processes, PDLLA is further decomposed into carbon dioxide and water, which are then safely excreted from the body.

PDLLA is recognized for its safety, having received approval from the **US FDA** and classified under its **GRAS (Generally Recognized as Safe)** designation since 1984.



WHY PROLUMA PLLA?

Developed through **advanced biostimulatory innovation by Genèse Labs France**, Proluma PLLA features a high-purity poly-L-lactic acid formula designed for deep collagen regeneration and structural volume restoration. Its crystalline particle composition offers powerful, long-lasting lifting effects, making it the preferred choice for treating deep wrinkles, volume loss, and age-related sagging. Proluma PLLA delivers gradual, natural-looking results that evolve beautifully over time—lasting up to two years.



Biostimulation Profile | Deeper, prolonged collagen stimulation



Ideal Age Group | Patients in their 40s to 60s



Treatment Areas | Chin, jawline, nasolabial folds, full-face volumization



Target Use | Facial contouring, structural support, long-lasting volume restoration



Recommended Injector Level | Best handled by experienced or advanced-level injectors due to deeper injection plane and post-care considerations

PROLUMA SPECIFICATIONS

INGREDIENTS	PLLA (Poly-L-lactic acid)	INJECTION FORCE	Approx. 3.5–4.0 N (depending on dilution)
MANUFACTURING METHOD	Freeze drying	HARMFUL RESIDUE	≤ 0.01 EU/mg (per CE and KFDA guidelines)
MOLECULAR WEIGHT	Approx. 100,000 – 300,000 DA	COMPOSITION	PLLA 41%, CMC 25%, Mannitol 34%
CANNULA	26G or 25G (based on practitioner preference)	DISSOLUTION TIME	2 hours
MICROSPHERES	40–60 µm		



EFFICIENCY OF PROLUMA PLLA

1. DEEP VOLUMIZATION & COLLAGEN REMODELING

Proluma PLLA is designed for structural restoration and long-term volume enhancement through deep collagen biostimulation. Its highly crystalline PLLA particles stimulate fibroblasts to produce new collagen over an extended period, progressively improving facial contours and firmness.

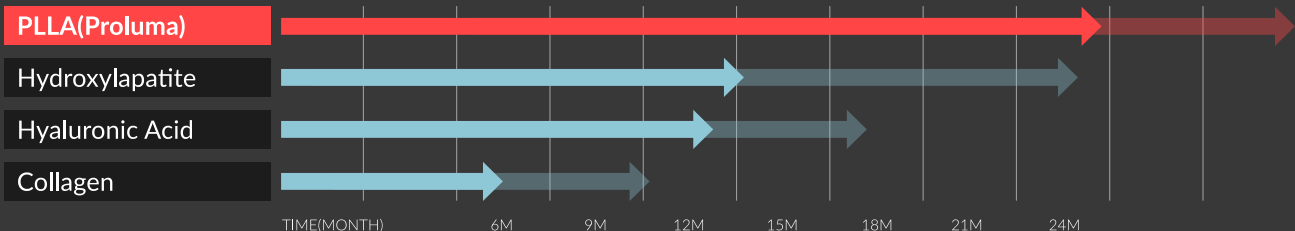
- By Week 4–6, initial fibroblast activation and ECM remodeling begin, with gradual improvement in skin density.
- By Week 12, collagen fibers begin to form a stable matrix around the PLLA microspheres, restoring facial volume naturally.
- By Weeks 16–24, advanced tissue remodeling occurs, delivering visible lifting, enhanced elasticity, and refined facial contours.

This slow, controlled process allows for natural-looking rejuvenation that evolves beautifully over time



2. LONG LASTING EFFECT

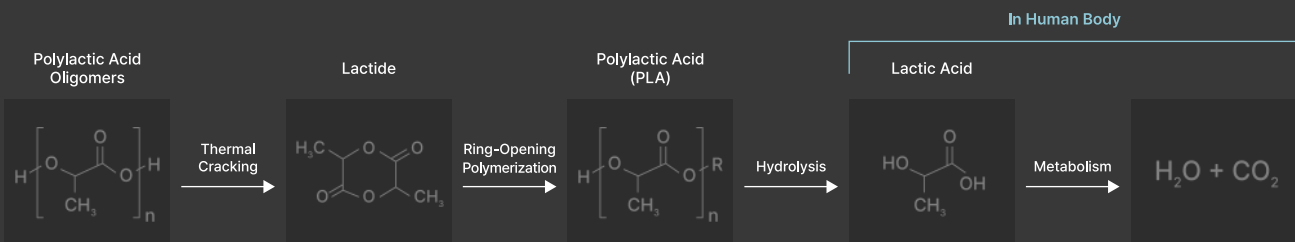
Proluma stands out by not only correcting wrinkles and folds but also ensuring lasting volumization across facial areas, offering a durable alternative to traditional fillers that target specific folds. Its effectiveness in enhancing natural facial volume through the stimulation of new collagen and tissue production contributes to its long-lasting results.



3. SAFETY : BIODEGRADABILITY

Proluma PLLA is manufactured using a highly purified, freeze-dried poly-L-lactic acid, ensuring safety, consistency, and biocompatibility. Once injected, it gradually hydrolyzes into lactic acid—a naturally occurring substance in the body—and is metabolized into carbon dioxide and water over time.

- GRAS-Approved by the US FDA (Generally Recognized As Safe)
- CE-Certified formulation developed by Genèse Labs France
- Biodegradable, non-toxic, and leaves no permanent residue in the body

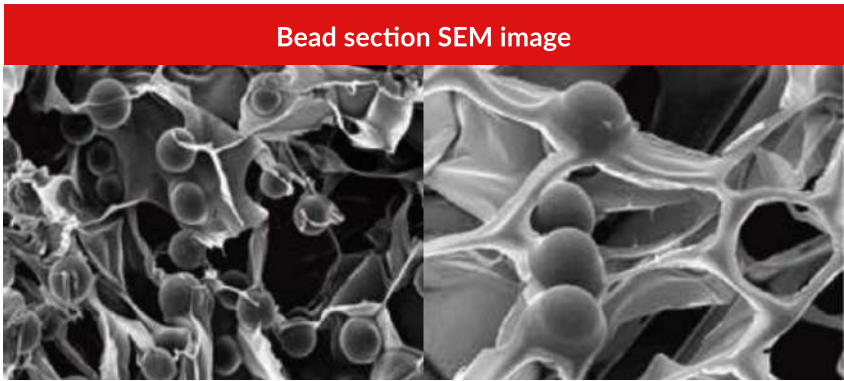


PROLUMA COMPONENTS

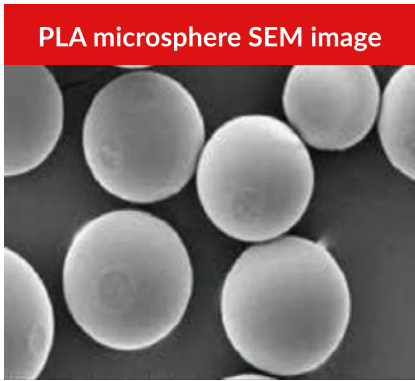
SODIUM CARBOXYMETHYLCELLULOSE(CMC)

Used as a suspending agent to create even distribution of PLA particles.

- Following reconstitution with water, undergoes hydration
- Widely used in medical and food industry, and "generally recognized as safe" (GRAS).
Included in the FDA Inactive Ingredients Guide for intradermal, intramuscular, intravenous, and subcutaneous injections.
- Widely used in parenteral (IV/IM) products



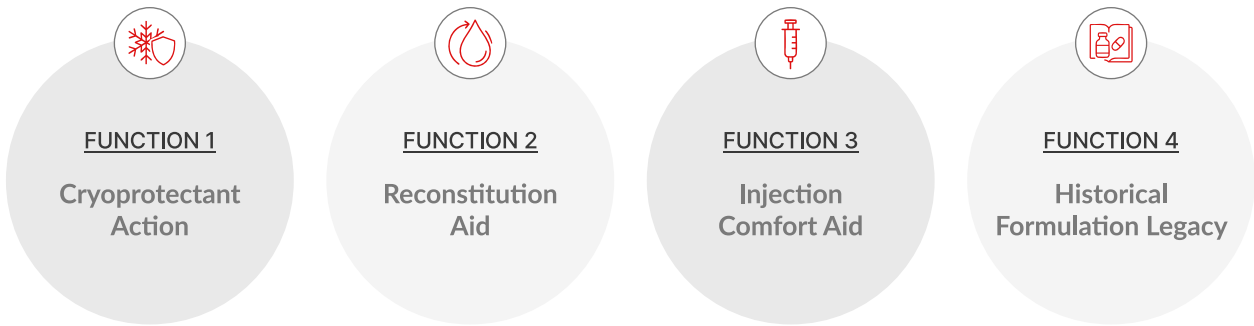
CMC remains in shape as it wraps around PLA particles.



PLA particles remain spherical after CMC has dissolved.

MANNITOL

PLLA needs mannitol to stabilize and assist in reconstitution due to its rigid and crystalline nature.



Why It's Not in PDLLA

- PDLLA has an amorphous structure that is more stable and less prone to damage during freeze-drying.
- PDLLA dissolves more easily and uniformly, often requiring shorter prep time and no mannitol to assist in dispersion.
- PDLLA formulations like Proluma are already optimized for soft injection due to their uniform, spherical particles.
- Newer PDLLA products are designed to reduce excipients and streamline formulations.

Why It's in PLLA

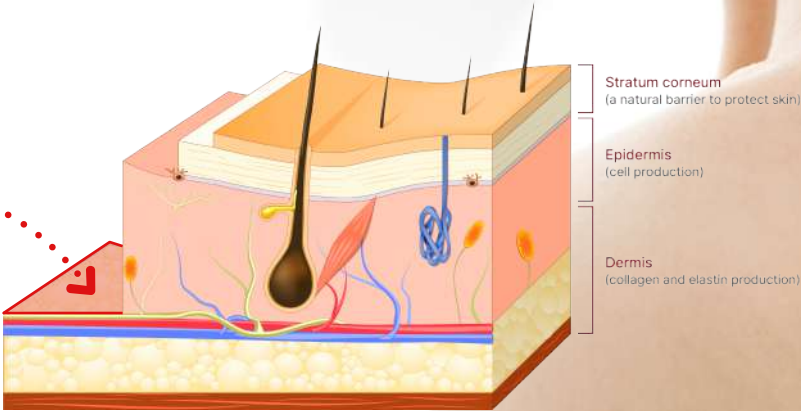
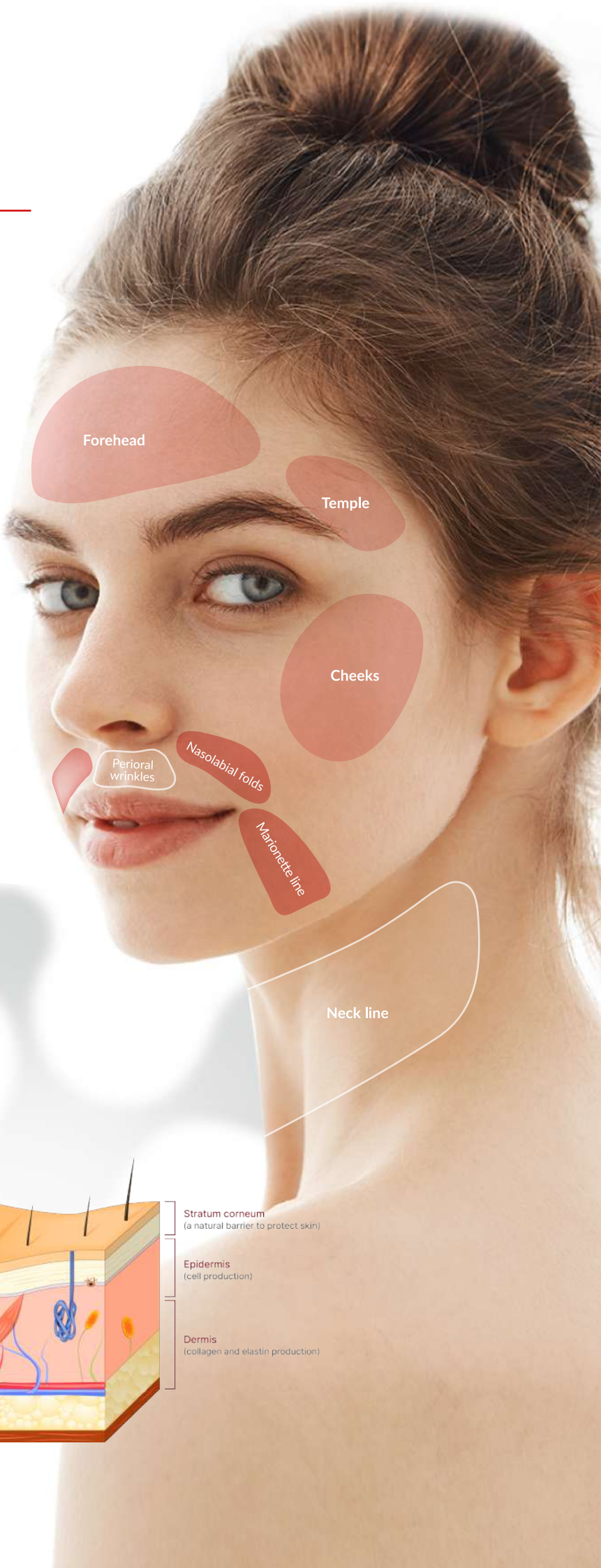
- PLLA's higher crystallinity makes it more fragile during freeze-drying; mannitol helps protect the microspheres.
- PLLA particles tend to clump and require longer reconstitution. Mannitol improves water penetration and dispersion.
- Mannitol may reduce injection force by improving suspension fluidity.
- Sculptra set the precedent, and mannitol remains standard in many PLLA formulas.

APPLICATION AREA

PRIMARY TARGET Dry, thin skin with fine wrinkles

SECONDARY TARGET Nasolabial folds

Inject into the deep dermis layer, where this method actively stimulates collagen production more effectively than conventional fillers.



DIRECTIONS FOR USE

PROLUMA PDLLA SUSPENSION PREPARATION & INJECTION GUIDE

Thirty minutes before the procedure, prepare a 9cc suspension by combining 7cc of Sterile Water For Injection (SWFI) and 2cc of lidocaine with the contents of the Proluma vial.



Remove cap and clean

Remove the flip-off cap and sanitize the penetrable vial stopper using an antiseptic.



Inject 7cc of Sterile Water For Injection (SWFI)

Connect an 18G needle to a sterile, single-use 7cc syringe and draw 7cc of Sterile Water For Injection (SWFI) into the syringe. Invert the vial, insert the needle through the stopper, and gradually inject the SWFI into the vial.



Agitate the vial upright prior to injection

Vigorously shake the vial by hand or use a single vial swirling agitator for approximately 1 minute to dissolve the excipients. Examine the vial for any undissolved lumps and, if necessary, continue shaking until they are dissolved.



Mix with Lidocaine

Immediately before treatment, cleanse the rubber cap of Proluma. Introduce 2cc of Lidocaine and then fill with the diluted solution using an 18G needle. It is important not to store the solution within the syringe for an extended period.



Withdrawing the suspension

Sanitize the stopper of the vial, then use an 18G single-use, sterile syringe, either 1- or 3ml, to withdraw the suspension.



Replace needle for injection

Before proceeding with the injection, replace the needle with a sterile 25G or 26G needle.

DIRECTIONS FOR USE

PROLUMA PLLA SUSPENSION PREPARATION & INJECTION GUIDE

7cc of Sterile Water for Injection (SWFI) / 2cc of 2% Lidocaine / 1 vial of PLLA (Poly-L-Lactic Acid).
Step-by-Step Instructions.



Open vial and sanitize

Open the PLLA vial by removing the flip-off or aluminum cap. Disinfect the rubber stopper with an alcohol swab.



Inject 5cc of Sterile Water For Injection (SWFI)

Inject 5cc of SWFI through the vial wall.



Shake and hydrate

Hold the vial upright and shake slowly by hand or using a swirling mixer for about 2-3 minute to dissolve the particles completely. If undissolved particles remain, continue shaking. After mixing, let the vial rest for approximately 60 minutes to complete hydration.



Reconstitution step

Shake the vial to mix well with the product and leave the preparation for about 60 minutes. Just before use, shake gently from side to side for 2~3 minutes.



Withdrawing the suspension

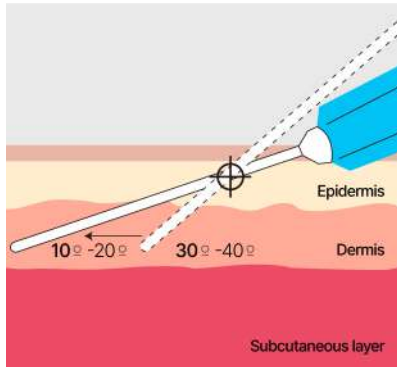
Take the suspension with 1ml or 3ml sterile syringe.



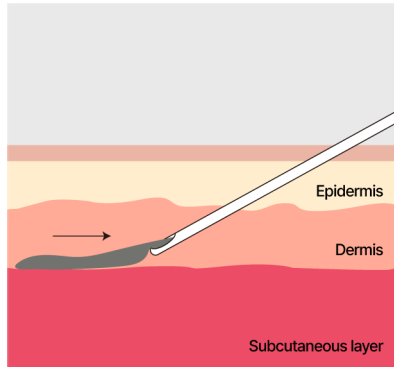
Replace needle for injection

Switch to a 25G or 26G needle before performing the injection.

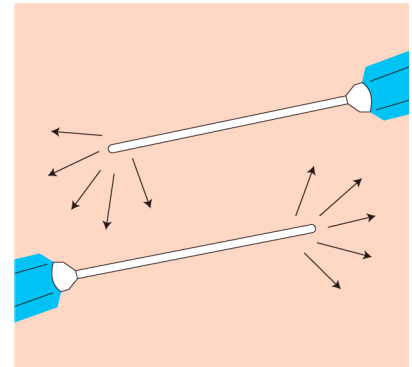
INJECTION TECHNIQUES



Once the needle tip reaches the deep dermal layer, adjust the needle angle to 10 ~20 degrees. Then, proceed to advance the needle within this deep dermal plane, ensuring it moves parallel to the skin's surface.



Administer Proluma injection parallel to the skin fold for optimal results.



Begin with the first injection at the base point, and subsequent injections should radiate outward from the first injection site. The diagram above illustrates a radial pattern observed upon completion of the final injection.

INJECTION RECOMMENDATIONS FOR OPTIMAL RESULTS

- **Maximum volume of Proluma PLA:** 0.1–0.2 ml per injection, spaced 0.5–1 cm apart.
- **Maintain Suspension Consistency:** Throughout the treatment process, it is imperative to regularly agitate the solution to ensure its homogeneous consistency is preserved.
- **Technique for Even Distribution:** Following every 3 to 4 injections, gently massage the treated area in a circular motion to ensure the even dispersion of the solution.
- **Pre-Treatment Preparation:** Prior to initiating the treatment, dispense a few drops of Proluma to verify that the needle is unobstructed and to expel any trapped air.
- **Needle Management:** Should you encounter any clogging during the procedure, promptly replace the needle to maintain the efficacy and smooth flow of the treatment.
- **Injection Strategy:** Start at the base of the nasolabial fold, injecting along its length parallel to the fold. Enhance coverage with radial injections perpendicular to the initial path for thorough treatment.
- **Dosage Control:** To ensure safety and effectiveness, the volume of Proluma administered per injection site should not exceed 1ml.

These guidelines are designed to facilitate a seamless and effective injection process, maximizing patient satisfaction and treatment outcomes with Proluma PLA.

POST TREATMENT CARE

- 1 Immediately after Proluma treatment, redness, swelling, and bruising may occur in the treated area.
- 2 To ensure Proluma distributes evenly in the area of contour deficiency, it is crucial at the end of the treatment session to manually massage the treated area in a circular fashion for a minimum of 2 minutes.
- 3 To minimize the risk of edema or bruising post-treatment, an ice pack should be applied to the treated area. (Avoid direct contact of the ice with the skin.)
- 4 Makeup may be applied a few hours after treatment if no complications arise. e. Avoid exposing the treated area to sun and UV light until any initial swelling and redness have subsided. Patients should be advised on appropriate sunscreen protection by their physician.

| BEFORE AND AFTER

BEFORE



AFTER



BEFORE



AFTER



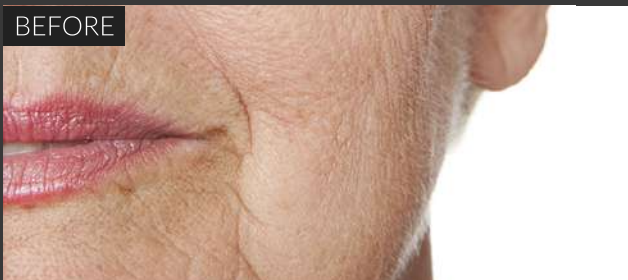
BEFORE



AFTER



BEFORE



AFTER



BEFORE



AFTER



BEFORE



AFTER



Contact Information

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