

VOLU ME& REGE NERA TION

BIORIV@LUMETRIA

MADE IN ITALY





REGENYAL LABORATORIES has a long history of scientific research and manufacture of products for AESTHETIC MEDICINE as well as for ORTHOPAEDICS, GYNAECOLOGY AND DENTISTRY. In particular, the company produces HYALURONIC ACID-based INTRA-DERMAL and INTRA-ARTICULAR injection products distributed all over the world, and, also works in the area of dermo-cosmetics offering a wide range of products. REGENYAL LABORATORIES stands out for operating in full respect of the NATURALNESS, HEALTH and HARMONY of the person, and, for the absolute safety



AESTHETIC MEDICINE / ORTHOPAEDICS / STOMATOLOGY / GYNECOLOGY



of the substances implemented in the manufacturing process. The company puts a lot of effort into the prestigious MADE IN ITALY brand and produces the injectables in compliance with the GREEN INJECTIONS standard. The HYALURONIC ACID used, is manufactured by FIDIA FARMACEUTICI and guarantees for the highest quality in terms of raw material purity. In the specific, the total absence of nucleic acids and proteins stands for: SUPERIOR QUALITY and ABSOLUTE SAFETY.

 **REGENYAL**
LABORATORIES





BIORIVOLUMETRIA

BIO

BIOCOMPATIBLE AND BIO-ABSORBABLE SUBSTANCES

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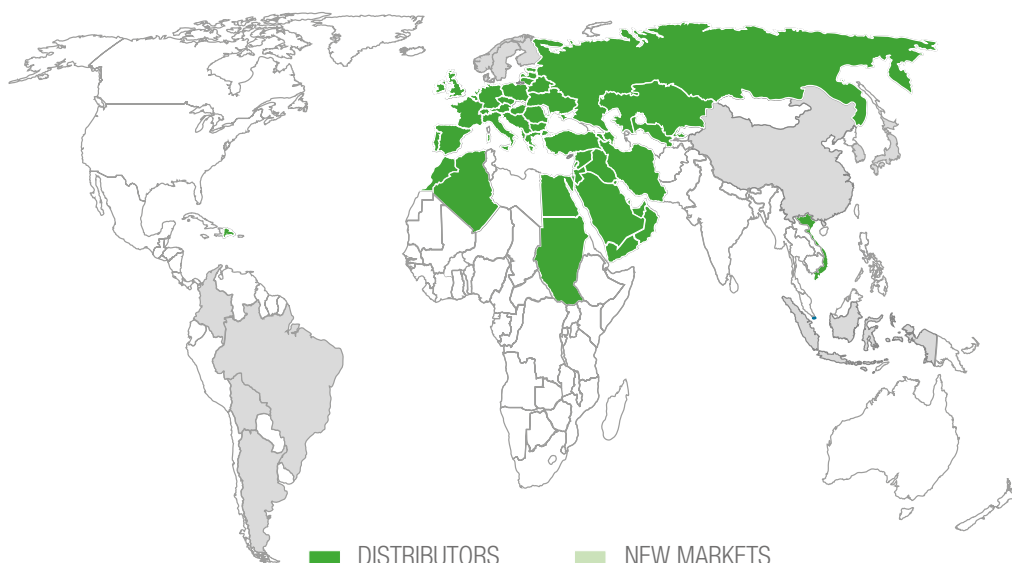
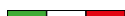
RE-GENERATION AND RE-STRUCTURING

VOLUMETRIA

CREATION OF NEW VOLUMES

SUPERIOR QUALITY AND ABSOLUTE SAFETY

MADE IN ITALY



■ DISTRIBUTORS

■ NEW MARKETS

REGENYAL LABORATORIES

has created BIORIVOLUMETRIA that makes it possible to PREVENT and REDUCE THE EFFECTS of skin aging with NATURAL RESULTS.

BIORIVOLUMETRIA enables:

- AUGMENTATION of VOLUME
- DERMAL and HYPODERMAL STIMULATION.

With an ageing face the adipose compartments move and become thinner, which, in some cases, may cause asymmetries of the face.

The absence of a structural support causes a relaxation of the soft tissues, making an aged face look hypo-trophic and loose.

IDEA/LIPS/SUPER IDEA/BIO-EXPANDER

These are the biorivolumetria products which, created with a CERTIFIED and PATENTED MANUFACTURING SYSTEM, restore facial volumes and improve skin texture.

Certification

ISO 9001

Quality Management Systems

ISO 13485

Quality Management Systems concerning medical devices

ISO 14001

International Standard for Organization Environmental Management

CE CERTIFICATION

By the Notified Body 0373 (Istituto Superiore di Sanità)

Scaffold Action

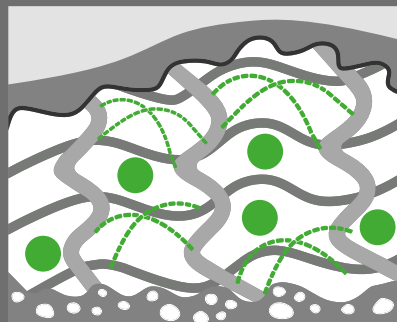
CROSS-LINKED HA - BIODEGRADABLE STRUCTURE

Plays the role of a structural platform that is partially inert and more resistant to absorption due to the cross-linkage

Re-Structuring Action

INTERCALATED SLOW-RELEASE HA - MORE ACTIVE BIOLOGICALLY

A gradually released bio-interactive HA that stimulates the DERMIS and the HYPODERMIS - interacting with the receptors of the endothelial cells and fibroblasts



Gentle cross-linking

Cross-linking two different molecular weights of HA results in a 3D matrix with optimized viscosity.

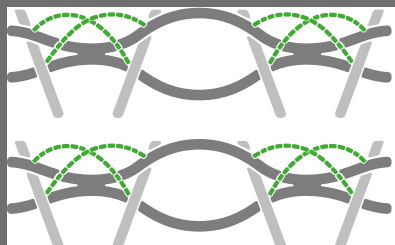


Fig. 1

Linear Intercalated Hyaluronic Acid

The Hyaluronic Acid interacts with the RECEPTORS and stimulates the Up-regulation of the receptor itself, which, on its turn, accelerates the cellular processes (Migration - Adhesion - Differentiation - Cellular Proliferation)

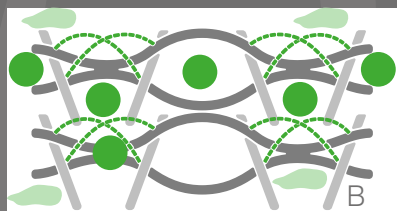
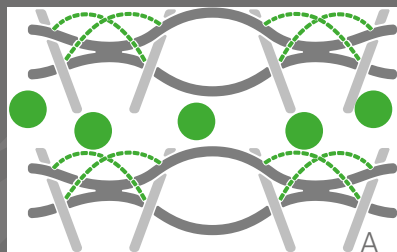


Fig. 2

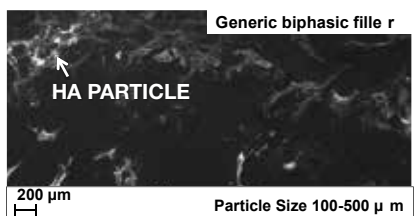
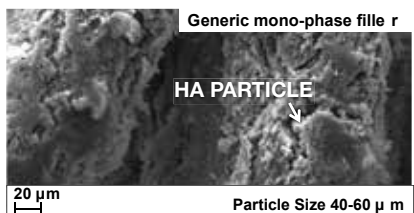
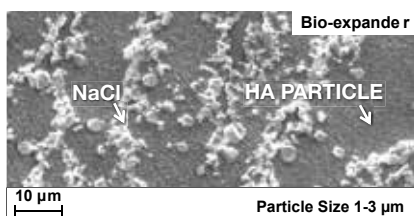
Actions on the Tissues

A cross-linked and an intercalated slow-release types of HA - are closely combined in the Biorivolumetria products:

- **CROSS-LINKED HA** - PERFORMS A STRUCTURAL VOLUMIZING FUNCTION
- **INTERCALATED SLOW-RELEASE** - PERFORMS A BIO-INTERACTIVE ACTION OF RECEPTOR STIMULATION

Structure under the microscope

The scanning electronic microscope pictures (SEM) show how, compared to fillers, the BIORIVOLUMETRIA products are MORE COMPACT and HOMOGENEOUS. This is possible because of the smaller dimensions of the cross-linked hyaluronic acid particles.



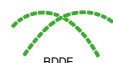
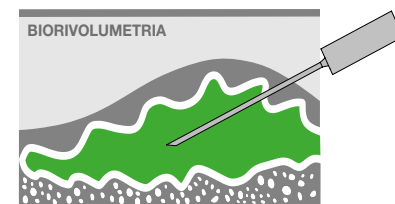
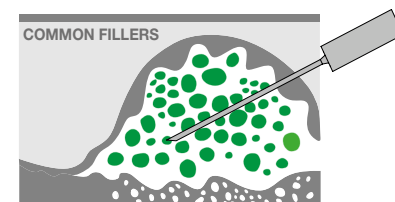
Interaction of the Linear Intercalated Hyaluronic Acid

The Hyaluronic Acid interacts with the RECEPTORS and stimulates the Up-regulation of the receptor itself, which, on its turn, accelerates the cellular processes (Migration - Adhesion - Differentiation - Cellular Proliferation)



Spreading within the tissues

The product spreads immediately within the tissues providing, thus, for a better tissue integration



BDDE



FREE HA



ENZYME



HA 2 MILLION DALTON

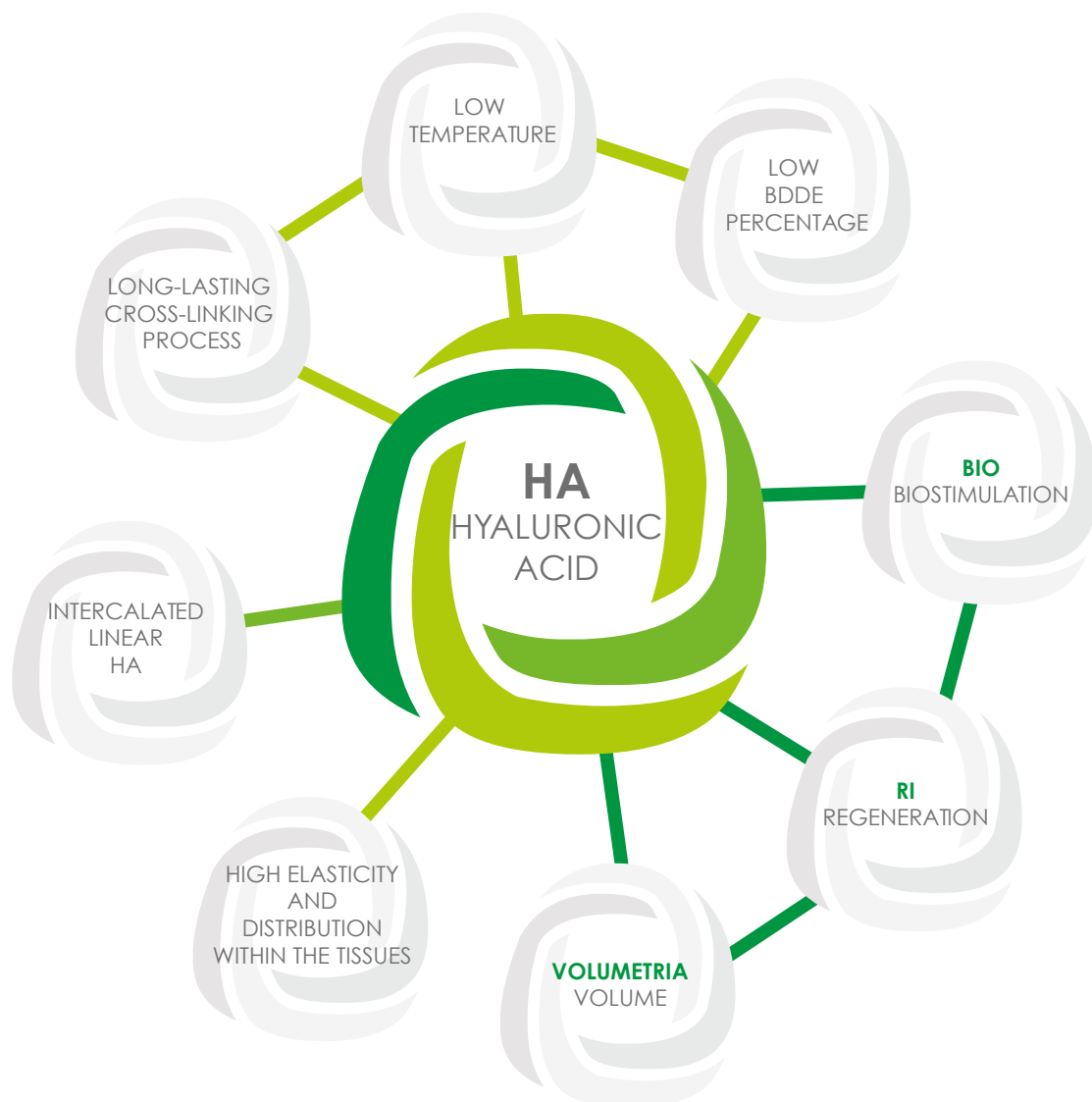


HA 1 MILLION DALTON

Manufacturing technology

PROPERTIES OF THE INNOVATIVE ITALIAN PATENT

**EXCLUSIVE PATENTED FORMULA THAT CAN STIMULATE
THE FORMATION OF VOLUMES AND RE-GENERATE SKIN TISSUES**



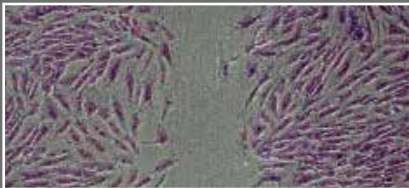
The Biorivolumetria products are MONO-PHASE GELS that are obtained through a long-lasting cross-linking process at low temperature: "GENTLE CROSS-LINKING" (Fig. 1). The long-lasting cross-linking allows for a better control of the degree to which the product is cross-linked, using lesser amounts of cross-linking agents. The low temperature allows to limit the de-polymerization of the raw material - the sodium hyalurate - thus, preserving its rheological properties. This, too, reduces the amounts of cross-linking agent to be used.

The intercalation (Fig. 2) helps to protect the linear Hyaluronic Acid against enzymatic degradation and to preserve its biological activity. Compared to common fillers, the particles are smaller which helps the product to better integrate and distribute within the tissues, avoiding the line-effect and providing for a natural correction. The innovative manufacturing process makes it possible to use lesser quantities of the cross-linking agent (BDDE), in comparison to common fillers with equal degree of viscosity (30% less).

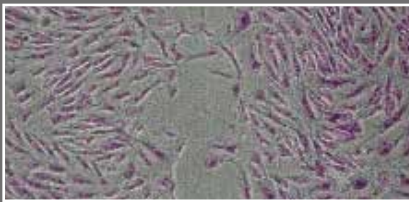
In vitro and in vivo studies in cooperation with the University of Siena

In Vitro studies on the immunofluorescence analysis of the junctional protein Occludin in endothelial cells of the human dermis.

ENDOTHELIAL MIGRATION ASSESSED WITH SCRATCH TEST AFTER 18 HOURS (HEMATOXYLIN AND EOSIN STAINED) ON HUMAN SKIN ENDOTHELIAL CELLS.

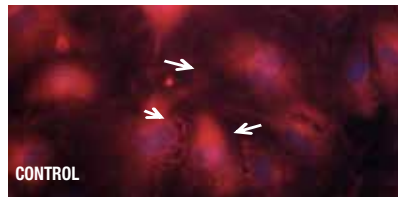


2% FOETAL SERUM

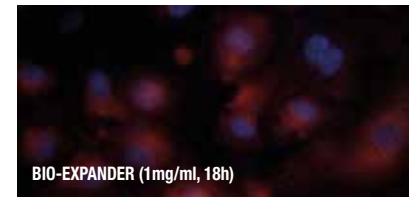


2% FOETAL SERUM

Bio-expander favours the migration of cells into the empty space (scratch)



CONTROL
THE OCCLUDIN KEEPS TOGETHER THE CELLS AND PREVENTS THEIR MIGRATION

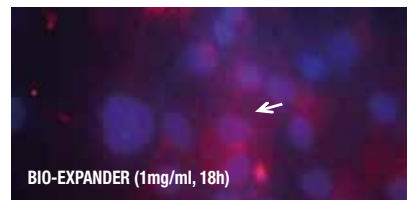


BIO-EXPANDER (1mg/ml, 18h)
BIO-EXPANDER INHIBITS THE SYNTHESIS OF OCCLUDIN AND PROMOTES THE MIGRATION OF THE CELLS

In vitro studies on the immunofluorescence analysis of CD-40 (cell membrane receptor)



CONTROL
CD-40 PARTICIPATES IN THE FORMATION OF NEW ENDOTHELIAL VESSELS

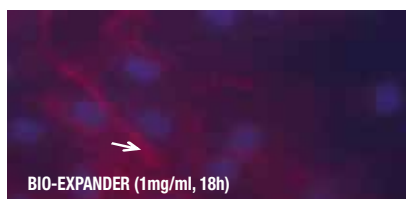


BIO-EXPANDER (1mg/ml, 18h)
BIO-EXPANDER STIMULATES THE UP-REGULATION ACTION OF THE CD-40

In vitro studies on the analysis of the immunofluorescence of Fibronectin (macro-molecule of the extra-cellular matrix)



CONTROL
THE FIBRONECTIN PARTICIPATES IN THE REGENERATION PROCESSES OF THE TISSUES



BIO-EXPANDER (1mg/ml, 18h)
BIO-EXPANDER STIMULATES THE EXPRESSION OF FIBRONECTIN

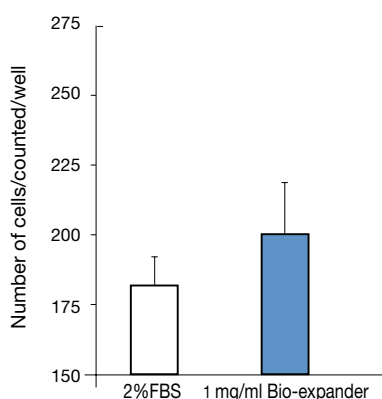
In Vivo studies

The in vivo studies conducted on mice have shown that BIO-EXPANDER favours the formation of new blood vessels in the subcutaneous implant after one week.



NEW BLOOD VESSELS

In vitro studies on the Proliferation of fibroblasts in human dermis (48 hours of incubation)



Tests show that the ability of Regenyal Idea **BIO-EXPANDER** to stimulate the proliferation of fibroblasts in human dermis is 40% higher than that of foetal bovine serum.



RAW MATERIALS - Purity of the raw materials free of polluting chemical substances

MANUFACTURING PROCESS - Industrial process ISO 14001certified and that respects the highest environmental standards

PATENTS - Developed with the aim to implement minimal amounts of external chemical substances

PACKAGING - The materials used for packaging are created from materials that respect the environment in compliance with the FSC standards



GREEN INJECTIONS is a new international safety standard applicable to injection products, and regarding their safety, the environment-friendliness of the manufacturing process and techniques, aimed at the obtainment of natural results and at the maintaining of natural beauty over the years.

GREEN PRODUCTS - Products of the highest quality created with the purest Hyaluronic Acid, with minimal levels of external chemical substances.

GREEN TECHNOLOGIES - New generation products created in Italy in compliance with the strictest rules on environment protection: limited waste, energy saving, water purification, recycling, use of machinery at low energy consumption (ISO 14001 certified).

GREEN TECHNIQUES - Injective techniques with cannulae or needles, developed by highly qualified medical experts, that guarantee high performance and safe treatments, while the risk of complications in the “difficult areas” is reduced to the minimum.

GREEN RESULTS - Visual “ecological” corrections that guarantee completely natural results!

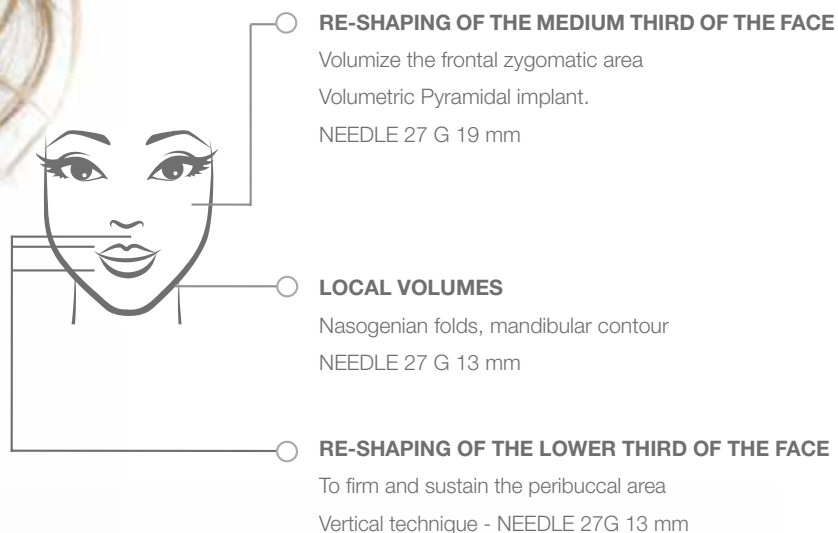
Face re-shaping

REGENYAL IDEA is an absorbable Biorivolumetria product based on cross-linked and intercalated Hyaluronic Acid obtained through bacterial fermentation. The product is meant for the correction of facial skin sagging of medium degree. Spreads naturally within the areas surrounding the implant, providing for a balanced and continuous distribution of the substance. The Hyaluronic Acid implemented is viscous and elastic to a degree that makes it possible to preserve the cohesion of the volume without interfering with the ability of the latter to adapt to individual morphology and to follow natural features. The gel's main properties are:

- HYDRATION
- DIFFUSIVITY
- PHYSIOLOGICAL CORRECTION
- LIFTING EFFECT

Indications

- RESTORATION OF VOLUMES
- CORRECTION OF THE LOWER ZYGOMATIC AND PRE-ZYGOMATIC AREA
- CORRECTION OF THE NASOGENIAN AREA
- CORRECTION OF THE MOUTH ANGLES
- CORRECTION OF THE CHIN AREA
- REDUCTION OF MEDIUM DEEP WRINKLES



IT IS RECOMMENDED TO REPEAT THE TREATMENT AFTER 7/8 MONTHS

Natural results

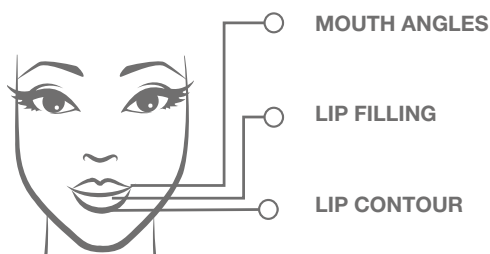
REGENYAL IDEA LIPS is a Biorivolumetria product - based on cross-linked and intercalated Hyaluronic acid - that naturally adapts to the lips optimizing them.

It is a mono-phase gel soft and safe, specifically designed for lips' treatments and presents:

- LOWER VISCOSITY (it can be injected with 30G needles)
- EFFICIENT POST-TREATMENT CONTROL
- HYDRATION AND IMPROVED TURGOR

Indications

- VOLUME INCREASE
- IMPROVEMENT OF THE SHAPE
- NATURAL EVERSION
- CORRECTION OF ASYMMETRIES



IT IS RECOMMENDED TO REPEAT THE TREATMENT AFTER 5/6 MONTHS



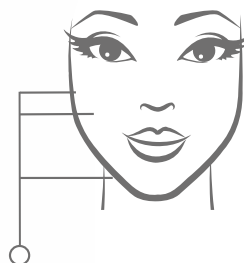
Volumizing Restructures and regenerates

REGENYAL IDEA BIO-EXPANDER is a remarkable Biorivolumetria product, that enables a complete rejuvenation of the face through volumetric correction and tissue re-structuring. The product integrates perfectly and follows natural shapes. Injected into the subcutaneous layer, the product will improve the skin in terms of elasticity, hydration, turgor, stimulation and recovery of the adipose tissues. The properties of **REGENYAL IDEA BIO-EXPANDER** are:

- REGENERATING
- RE-STRUCTURING
- VOLUMIZING

Indications

- CHEEKS
- PERI-ZYGOMATIC AREA
- MANDIBULAR AREA
- HANDS
- DECOLLETÉ



NATURAL RE-SHAPING OF FACIAL VOLUMES

MICRO-CANNULA 37mm 27 G

Designed specifically to be used with micro-cannula, the product spreads perfectly within the tissues following the natural shapes of the face. As big amounts of water are attracted, the product immediately **BIO-EXPANDS** rebalancing the volumes of the face. The native intercalated Hyaluronic Acid contained, provides for the re-structuring of tissues.



IT IS RECOMMENDED TO REPEAT THE TREATMENT AFTER 4/5 MONTHS

Reshaping Deep facial volumes

REGENYAL SUPER IDEA is an absorbable Biorivolumetria product (sterile, apyrogenic and physiological gel) to be used as filling material for:

- VOLUME RESTORATION
- CORRECTION OF DEEP SKIN SAGGING

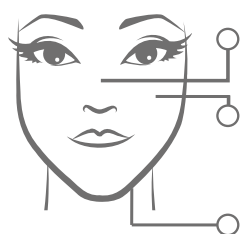
Its main component is cross-linked and intercalated Hyaluronic Acid of non animal origin and obtained through bacterial fermentation.

Indications

- VOLUMETRIC AUGMENTATION OF CHEEKBONES
- FRONTAL MALAR AREA
- CORRECTION OF DEPRESSED NASAL ANGLE
- RE-DEFINITION OF THE MANDIBULAR CONTOURS
- PLASTIC CORRECTION OF THE CHIN
- RHINOPLASTY

Injection points

- DEEP HYPO-DERMA
- ABOVE PERIOSTEUM
- DEEP HYPO-DERMA AND ABOVE THE PERIOSTEUM



NOSE AREA

CHEEKBONES

38mm 25G micro-cannula

CHIN

38mm 25G micro-cannula



IT IS RECOMMENDED TO REPEAT THE TREATMENT AFTER 8/9 MONTHS



PYRAMIDAL IMPLANT - Correction of the zygomatic area



NASOGENIAN WRINKLES - Mouth angles



VOLUME INCREASE - Improvement of the shape – Eversion



CORRECTION OF ASYMMETRIES - Increase of volume



RADIAL TECHNIQUE WITH MICRO-CANNULA



BEFORE



AFTER

CORRECTION OF THE LOWER ZYGOMATIC AREA

Super ^{REGENYAL}
idea



BEFORE



AFTER

VOLUMETRIC AUGMENTATION OF THE ZYGOMATIC AREA



BEFORE



AFTER

RE-DEFINITION OF THE MANDIBULAR CONTOUR

BIORIVOLUMETRIA Kit

Naturalness and harmony of the results








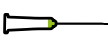

BIORIVOLUMETRIA KIT is a set of products that enables the physician to perform various rejuvenation treatments in specific areas of the face freely and with more comfort. A complete range created to satisfy the needs of every person.

Biorivolumetria kit contains 4 packages of injection products:

- **IDEA** 1x1 ml
- **LIPS** 1x1 ml
- **SUPER IDEA KIT** - 1 kit - 3 X 1 ml
- **BIO-EXPANDER** 1 kit - 3 X 1.1 ml



Data sheet

	 COMPOSITION	 DOSAGE	 MOLECULAR WEIGHT	 HA CONCENTRATION	 INDICATIONS	 PACKAGE	 CROSS-LINKING AGENT	 NEEDLES & CANNULAE	 DEEP OF INJECTION	 DURATION
IDEA	CROSS-LINKED AND LINEAR INTERCALATED HYALURONIC ACID	1 ML	1M DALTON + 2M DALTON CROSS-LINKED + 7% LINEAR INTERCALATED HYALURONIC ACID 1M DALTON	25 MG/ML	NASOLABIAL FOLDS DEEP WRINKLES	1 PRE-FILLED SINGLE USE SYRINGE	●●●●● RESIDUAL BDDE <0.1 PPM	1 NEEDLE 27G X 13 MM 1 NEEDLE 27G X 19 MM STERIMEDIX (CE 0120)	HYPODERMIS	7/8 MONTHS
LIPS	CROSS-LINKED AND LINEAR INTERCALATED HYALURONIC ACID	1 ML	1M DALTON + 500K DALTON CROSS-LINKED + 8% LINEAR INTERCALATED HYALURONIC ACID 500K DALTON	25 MG/ML	LIPS VOLUME AUGMENTATION LIPS CONTOUR BARCODE	1 PRE-FILLED SINGLE USE SYRINGE	●●●● RESIDUAL BDDE <0,1 PPM	1 NEEDLE 27G X 13 MM 1 NEEDLE 30 G X 13 MM STERIMEDIX (CE 0120)	DERMIS HYPODERMIS	5/6 MONTHS
BIO-EXPANDER	CROSS-LINKED AND LINEAR INTERCALATED HYALURONIC ACID	1.1 ML	1M DALTON + 2M DALTON CROSS-LINKED + 10% LINEAR INTERCALATED HYALURONIC ACID 500K DALTON	25 MG/ML	FACE NECK DÉCOLLETÉ HANDS	3 PRE-FILLED SINGLE USE SYRINGES	●●●● RESIDUAL BDDE <0,1 PPM	1 NEEDLE 26G X 13 MM 1 CANNULA 27G X 37 MM NEEDLE CONCEPT (CE 0499)	HYPODERMIS	4/5 MONTHS
SUPER IDEA	CROSS-LINKED AND LINEAR INTERCALATED HYALURONIC ACID	1 ML	1M DALTON + 2M DALTON CROSS-LINKED + 5% LINEAR INTERCALATED HYALURONIC ACID 1M DALTON	25 MG/ML	CHEEKBONES VOLUME CHIN RHINOPLASTY	1 OR 3 PRE-FILLED SINGLE USE SYRINGES	●●●●● RESIDUAL BDDE <0,1 PPM	1 OR 3 NEEDLES 23G X 19 MM 1 OR 3 CANNULAE 25G X 38 MM TSK (CE 0123)	DEEP HYPODERMIS ABOVE THE PERIOSTEUM	8/9 MONTHS

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