

# **BIORIV@LUMETRIA**

TIMELESS BEAUTY









## Regenyal Laboratories

For many years now the company has been working in the field of scientific research and manufacturing of devices for AESTHETIC MEDICINE, ORTHOPAEDICS and DENTISTRY. Specialized in the manufacturing of INTRADERMAL and INTRA-JOINT INJECTIVE products based on HYALURONIC



ACID, distributed in Italy and abroad. REGENYAL LABORATORIES also enters the field of dermo-cosmetics with a wide range of products. The company stands out from the others due to the absolute safety of substances used and to the sustainable process that respects the naturalness, health and harmony of the person. A lot of effort is put into the prestigious MADE IN ITALY brand; the injectives are manufactured in compliance with the GREEN INJECTIONS standard.

## BIORIV@LUMETRIA

High degree of scientificity, studies and potential of the laboratories are at the basis of BIORIVOLUMETRIA, a method designed by REGENYAL LABORATORIES, which prevents and treats skin ageing with natural results; a true revolution in anti-aging. Currently, the biorivolumetria products created with the CERTIFIED and PATENTED MANUFACTURING SYSTEM are:

- REGENYAL IDEA LIPS
- REGENYAL SUPER IDEA
- REGENYAL IDEA BIO-EXPANDER
- REGENYAL IDEA



### 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)





## Biorivolumetria in skin ageing

# BIORIVOLUMETRIA makes it is possible to COMBAT AGEING through AUGMENTATION of VOLUME and DERMAL AND HYPODER-MAL STIMULATION

When a face gets older the adipose compartments move and becomes thinner, which, in some cases, causes asymmetries of the face. The lack of a structural support, on its turn, causes a relaxation of soft tissues, that makes the aged face look hypo-trophic and loose.

RESTORATION OF VOLUMES AND BOOSTING OF A TISSUE RESTRUCTURING PROCESS

## 3 concepts in the name Bio-Ri-Volumetria

**BIO** - BIOCOMPATIBLE AND BIO-ABSORBABLE SUBSTANCES **RI** - RE-GENERATION AND RE-STRUCTURING **VOLUMETRIA** - CREATION OF NEW VOLUMES

#### HIGHLY PURE HYALURONIC ACID

The HYALURONIC ACID supplied by FIDIA FARMACEUTICI, stands for the maximum quality standard of the manufacturing process in terms of raw material purity; in the specific, the complete absence of nucleic acids and proteins guarantees for:

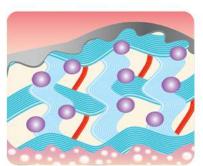
- SUPERIOR QUALITY
- ABSOLUTE SAFETY

#### BIORIV@LUMETRIA

### 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





#### SCAFFOLD ACTION (Cross-linkad 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

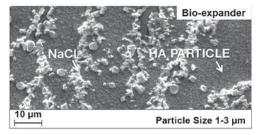
## (Intercalated slow-realease HA) more active biologically

A gradually released bio-interactive HA that stimulates the DERMIS and the HYPODERMIS

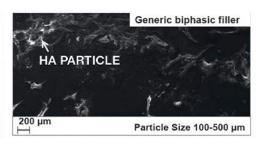
- interacting with the receptors of the endothelial cells and fibroblasts

## Structure under microscope

The scanning electronic microscope pictures (SEM) show how the Biorivolumetria products are more compact and homogeneous than the fillers.





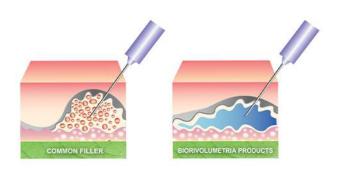


## Manufacturing technology

The Biorivolumetria products are mono-phase gels manufactured with a long-lasting cross-linking process at low temperature — "gentle cross-linking" (FIG.1). The slow mixing allows for the cross-linking agent (BDDE) to widespread better and in a more uniform manner. The amount of BDDE used is 30 per cent lower than in the majority of other products with the same degree of viscosity available on the market. Moreover, in the case of BIO-EXPANDER three molecular weights of hyaluronic acid are implemented: at 1 million, 2 million and 500 thousand Dalton; the latter corresponds to 10 per cent of native and intercalated HA (FIG.2). Differently long HA chains allow for a better calibration of the product's viscosity.

## Spreading within the tissues

THE PRODUCT SPREADS IMMEDIATELY WITHIN THE TISSUES PROVIDING, THUS, FOR A BETTER TISSUE INTEGRATION



## Gentle cross-linking

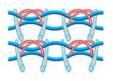
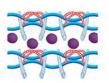


Fig. 1

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

## Native Intercalated Hyaluronic Acid



With the intercalation process a cross-linked layer is alternated with a free native layer during the production phases.

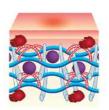


Fig. 2

The intercalated HA is protected against enzymatic degradation and is released slowly



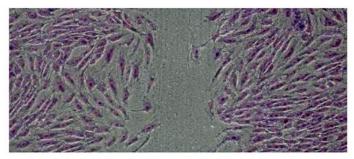
## Interaction of the Native Intercalated Hyaluronic Acid



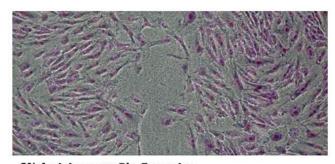
The Hyaluronic Acid interacts with the RECEPTORS and stimulates the Up-regulation of the receptor itself, which, on its turn, accelerates the cellular processes (Migration – Adhesion – Differentiation – Cellular Proliferation)

### In vitro studies

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

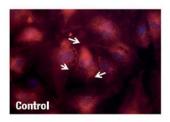


2% foetal serum

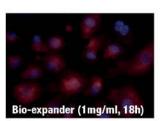


2% foetal serum+Bio-Expander
Enhanced cell migration into the free space (scratch)

Immunofluorescence analysis of the tight junction protein Occludin in human dermal endothelial cells



THE OCCLUDIN KEEPS TOGETHER THE CELLS AND PREVENTS THEIR MIGRATION

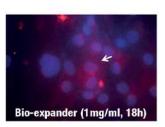


BIO-EXPANDER INHIBITS THE SYNTHESIS OF OCCLUDIN AND PROMOTES THE MIGRATION OF THE CELLS

Immunofluorescence analysis of the cellular membrane CD-40 receptor



CD-40 PARTICIPATES IN THE FORMATION OF NEW ENDOTHELIAL VESSELS



BIO-EXPANDER STIMULATES THE UP-REGULATION ACTION OF THE CD-40

Immunofluorescence analysis of the Fibronectin, macro-molecule of the extracellular root



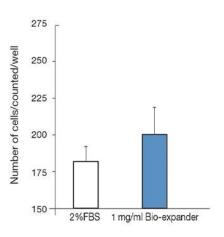
THE FIBRONECTIN PARTICI-PATES IN THE REGENERA-TION PROCESSES OF THE TISSUES



BIO-EXPANDER STIMULATES THE EXPRESSION OF FIBRONECTIN

Proliferation of human dermal fibroblasts (48 h 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



## In Vivo Studies

IN VIVO STUDIES PERFORMED ON MICE HAVE SHOWN THAT BIO-EXPANDER STIMULATES THE FORMATION OF NEW BLOOD VESSELS IN THE SUBCUTANEOUS IMPLANT AFTER ONE WEEK.



New blood vessels



## Bio Process

#### A Specific Controlled And Certified Manufacturing Method





## Green Injections

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!



## Hypo-Volumes of the face

The face, in its morphological variations, has peculiar properties linked to the distribution of volumes across various areas, such as the bone and muscular structure and compartmental fat. The age-related physiognomic alterations are compromised by:

- A PROGRESSIVE REDUCTION OF FLUID IN THE JUNCTION AND EXTRA-CELLULAR SPACES
- A STRUCTURAL ALTERATION OF THE DERMAL AND EPIDERMAL CONFIGURATION

## WHEN CHOOSING A BIORIVOLUMETRIA PRODUCT, THE FACIAL HYPO-VOLUMES OF EACH PATIENT MUST BE TAKEN INTO ACCOUNT

## Local Hypo-Volumes (LH)

- FILLING
- RECEPTOR STIMULATION
- ELASTICITY
- YOUNGER PATIENS
- THE CONSTITUTIONAL ASPECT PREVAILS
- SOFT AND BONE TISSUES ARE NOT OR ARE POORLY INVOLVED





The hypo-volumetric aspect prevails over the de-structuring, whereby the latter is in its early or a little developed stage. In addition, a correct hydration and extra-cellular osmolarity are found.

## Hypo-Volumetric De-Structuring (HD)

- DIFFUSIVITY
- HYDRATION
- SOFTNESS
- FLEXIBILITY
- RECEPTOR STIMULATION
- OLDER PATIENTS
- MORE WIDESPREAD HYPO-VOLUMES
- INVOLVEMENT OF DERMAL-HYPODERMAL BONE STRUCTURES





The reduction of the hypodermal layer is more widespread and is related to an advanced damage of the dermal structure and to a reduced concentration of fluid inside the extra-cellular compartment.





**BIO**RIV@LUMETRIA

## VOLUME LIP









**AFTER** 



BEFORE



**AFTER** 

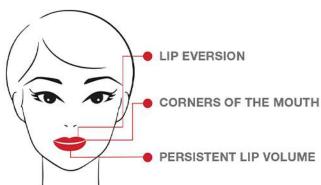


 $\textbf{REGENYAL IDEA SUPER LIPS} \ \ \text{is a more cross-linked and structured product with less free HA}.$ 

It also retains high elasticity but with increased volumetric activity. Thanks to these features,

it is suitable for creating a certain degree of volume and eversion of the lips.

The product can be injected close to the outer surface of the mucosa to provide a strong eversion, thus also reducing the risk of compromising the labial artery, which in most cases runs more posteriorly.



- 27 G NEEDLE / 25 G CANNULA
- VERTICAL OR LINEAR TECHNIQUE



## **SUPER Lips**

BIORIVOLUMETRIC MONO-PHASE, CONTAINING SOFT HYALURONIC ACID FOR THE LIPS, WITH A NATURAL VOLUME INCREASE.

#### LIP

#### **VOLUME INCREASE**

- PERSISTENT NATURAL VOLUME
- NATURAL EVERSION
- IMPROVED SHAPE
- CORRECTION OF ASYMMETRIES
- HIGH CROSS-LINKING
- LESS FREE HA
- HIGH ELASTICITY
- GREATER PERSISTENCE
- MEDIUM VISCOSITY
- ABSOLUTE SAFETY







## Bio-expander

## Rejuvenation is possible

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
- VOLUMIZING
- RE-STRUCTURING

### Indications

- CHEEKS
- PERI-ZYGOMATIC AREA
- MANDIBULAR AREA

### **BIO**RIV@LUMETRIA

INDICATED IN CASE OF HYPO-VOLUMETRIC DE-STRUCTURING (HD)



### NATURAL RE-SHAPING OF FACIAL VOLUMES

MICRO-CANNULA 37mm 27 G

Scheme

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.



## Super Deal

## Remodelling deep volumes of the face

REGENYAL SUPER IDEA is a re-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

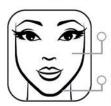
ABOVE PERIOSTEUM

- DEEP HYPO-DERMA AND ABOVE THE PERIOSTEUM

### **BIO**RIV@LUMETRIA

INDICATED IN CASE OF DEEP LOCAL HYPO VOLUMES (LH)

### Scheme



O CHEEKBONES

38mm 25G micro-cannula

CHIN

38mm 25G micro-cannula

It is recommended to repeat the treatment after 12 months











- HYPO-VOLUMETRIC DE-STRUCTURINGS
- RESTORATION OF FIRMNESS
- CORRECTION OF THE PERI-ZYGOMATIC AREA
- CORRECTION OF THE MANDIBULAR AREA
- CORRECTION ON CHEEKS

- VOLUMETRIC ACTION
- RECEPTOR STIMULATION
- DIFFUSIVITY
- HYDRATION
- SOFTNESS
- FLEXIBILITY
- REGENERATION





- DEEPER LOCAL HYPO-VOLUMES
- RESTORATION OF DEEPER VOLUMES
- FILLING OF THE ZYGOMATIC AREA
- CORRECTION OF THE CHIN AREA
- RHINOPLASTY

- RECEPTOR STIMULATION
- FILLING STIMULATION
- VOLUMETRIC ACTION
- FLEXIBILITY





- LIP EVERSION
- CORNERS OF THE MOUTH
- PERSISTENT LIP VOLUME

- LIP VOLUME INCREASE
- HIGH CROSS-LINKING
- HIGH ELASTICITY
- IMPROVED SHAPE
- ABSOLUTE SAFETY

## BIORIVOLUMETRIA

## Bio-expander









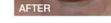
Radial technique with micro-cannula

Correction of the lower zygomatic area













Re-definition of the mandibular contour

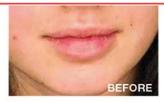


## SUPER Lips

Volumetric augmentation of the zygomatic area













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