

The product is solely intended to be used by medical personnel. Do not use for applications other than indicated in this package leaflet.

### **DESCRIPTION**

Regenyal Idea SUPER Lips is a resorbable medical device (sterile, apyrogenic and physiological gel) to be used as filler for the correction of medium and deep skin sagging on the face and to increase lip volume and contour. The main component is cross-linked hyaluronic acid of non-animal origin, produced by bacterial fermentation.

### **COMPOSITION**

Cross-linked hyaluronic acid ..... 25 mg/g  
Phosphate buffered saline, Water for injections solutions ..... q.s. 1 g

### **PACKAGE 1x1ml**

- package leaflet
- sealed blister containing 1 single-dose/single-use pre-filled sterile syringe
- adhesive tabs to be applied to the patient card for product traceability
- 3 needles and 1 cannula

### **METHOD OF ACTION**

Regenyal Idea SUPER Lips is injected into the skin tissue for the supplementation of the extracellular matrix and to increase intracutaneous volume, or for the treatment of cutaneous depressions due to wrinkles and scarring.

### **INTENDED USE**

Regenyal Idea SUPER Lips is an implantable medical device produced in compliance with Directive 93/42/EEC MDD, intended for the treatment of imperfections in the following areas of the face:

- nasolabial folds
- perioral wrinkles
- acne and facial scars
- glabellar wrinkles
- forehead wrinkles
- areas of the face requiring enrichment of the facial tissue (ex. cheeks, chin, cheekbones, lips) with a temporary increase in volume of the soft tissues.

The outcomes of the procedure depend on skin type and the nature of the blemishes, with results being the better the less noticeable the nature of the defect.

### **DIRECTIONS FOR USE**

Prior to any procedure with Regenyal Idea SUPER Lips, the doctor must conduct adequate anamnesis and an overall assessment of the patient's condition, to ensure the absolute absence of contraindications to the implant.

The areas to be treated must be identified and assessed based on criteria to do with lines and symmetry one must adhere to.

The procedure may be performed under local anaesthesia for lip treatments in order to ensure the necessary comfort to the patient.

The physician should inform the patient beforehand on the methods of the procedure, its nature, warnings, precautions and possible individual outcomes, the potential adverse responses, the expected duration of the implant and the possible need for supplementary procedures for maintenance and/or detailed definition of the result achieved. The area of the procedure should be cleaned with antiseptic solutions before implantation.

Extract the syringe from the blister, remove the top as shown in the figure and screw the needle or the cannula to the luer-lock, complete with protection.

Only remove the cover just before performing the procedure.

Regenyal Idea SUPER Lips is administered with a sterile needle compliant with Luer-Lock standards with standardised fittings, included in the package. The implant should be performed in the top/middle dermis; the procedure is, however, at the physician's discretion and depends on the correction to be performed and the chosen implantation method.

At the end of the procedure it is advisable to perform a gentle massage of the treated area for the implant to be optimally distributed.

REGENYAL  
idea

SUPER Lips



CROSS-LINKED  
HYALURONIC ACID

CE  
0373



**AGO / NEEDLE 27G x 13mm**



**AGO / NEEDLE 27G x 19mm**



**AGO / NEEDLE 23G x 19mm**



**CANNULA / CANNULA 25G x 38mm**



**STERILE R**



TSK Laboratory, Japan  
2-1-5 Hirayanagi-Cho,  
Tochigi-Shi, Tochigi Ken  
Japan

**EC REP**

Emergo Europe  
Molenstraat, 15  
2513 BH The Hague  
The Netherlands

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SUPER Lips



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HYALURONIC ACID



0373

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