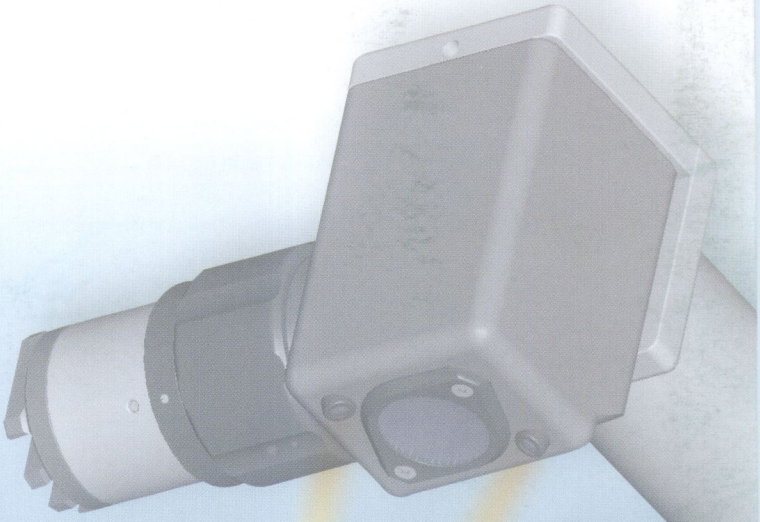
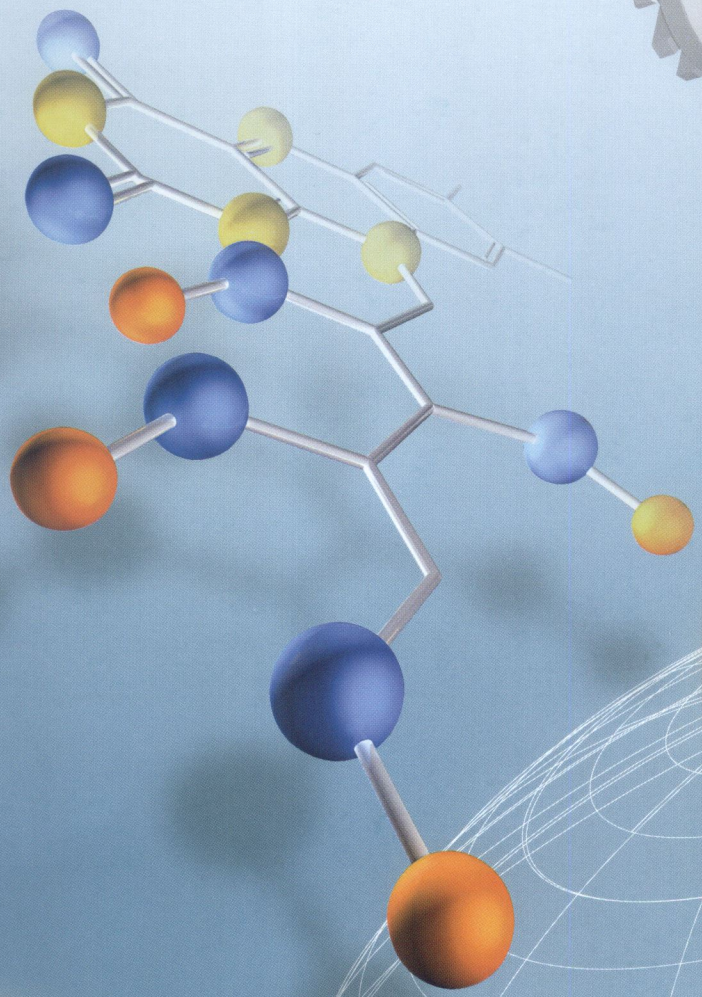
RICROLIN®

VEGA

Innovative approach in the treatment of keratoconus





RICROLIN®

(Riboflavina 0,1%)
Ophthalmic solution for parasurgical use

RICROLIN IS A STERILE AND SINGLE-DOSE FORMULA, IN COMPLIANCE WITH GLP

RICROLIN DOES NOT CONTAIN PRESERVATIVE AGENTS

Riboflavin in Cross-linking:

- Absorbs UV light rays
- Produces oxidative reagent species
- Protects the endothelium and the sensitive ocular structure (riboflavin reduces the intensity of the UV light rays by 95%)

Stability

Stability tests (accelerated by 5 months compared to the 20 months of ordinary stability) demonstrate that the riboflavin concentration is higher than 97%

Data collected after 24 months

(in accordance with the Siena Eye Cross Project – A. Caporossi, C. Mazzotta, S. Baiocchi - Università di Siena)

PARAMETER	*FOLLOW UP (AVERAGE RESULTFROM 44 EYES TREATED)*
K TOPOGRAPHIC VALUE	*REDUCTION OF > 2 D*
UCVA	*IMPROVEMENT OF 2,7 SNELLEN LINES*
BSCVA	*IMPROVEMENT OF 1,9 SNELLEN LINES*
SYMMETRY	*IMPROVEMENT > 70%*
ABERRATIONS	*SIGNIFICANT REDUCTION IN COMATIC ABERRATIONS*

Keratoconus was stabilized in 100% of the patients

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VEGA

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Technical characteristics

LCD Monitor

- Colour micro-telecamera with LCD monitor integrated within the optical head to capture images of the procedure in real time
- Narrow LED array for UV light distribution
- Adjustable iris diaphragm from 4 to 11 mm to vary the area to be treated, while maintaining the 3mW/cm² power density constant
- Collimation system with intermittent red light LED for accurate focalisation
- Coaxial green fixation light

- Balanced arm on wide wheeled base for comfortable use
- Control Pedal
- Wide working range (54mm) for confortable manoeuvering

FIRST WITH CERTIFICATION ★ FIRST WITH CERTIFICATION ★

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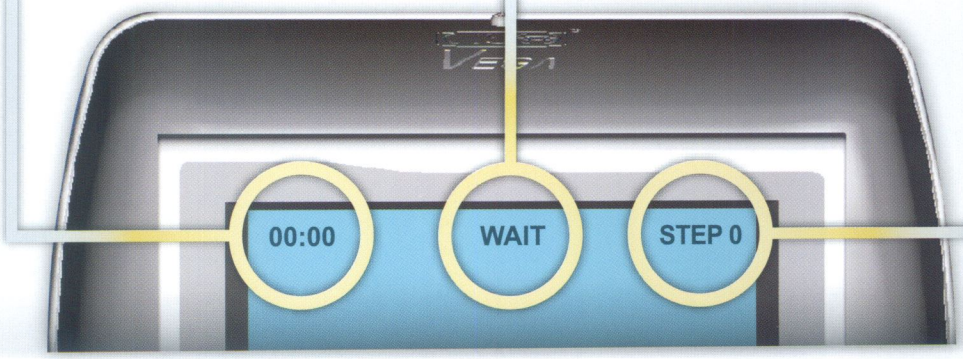
Easy to use

Video-acoustic system with monitor provides the operator with all scanning information on time and procedure phases.

Timing of each step is recorded in minutes and seconds

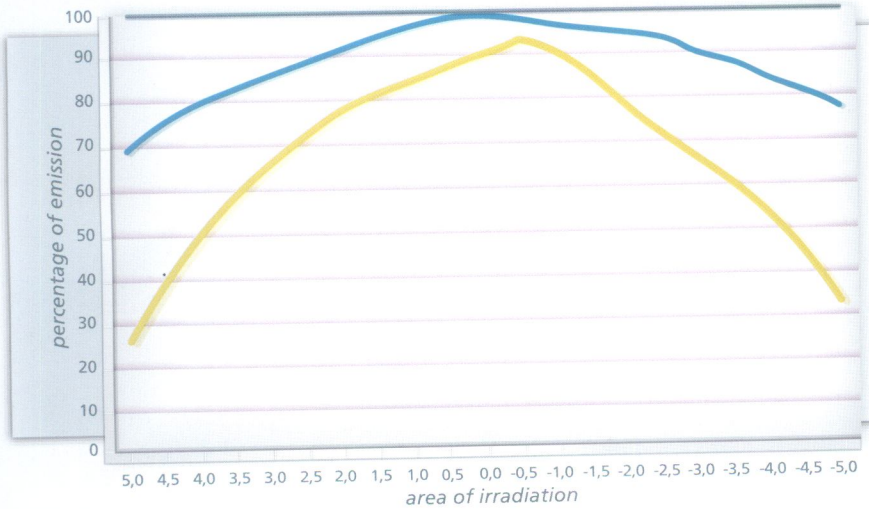
Indicates the STATUS of the sistem (WAIT, RUN, PAUSE, RESET)

Indicates each STEP of the procedure



Control pedal guarantees sterility and separate operating activity of operator

Emission consistency



The single LED provides the energy needed ensuring more than 90% on a surface area of irradiation of max. 11 mm diameter - emisssion percentage

Others instruments
CSO Vega
Max

RICROLIN®

(Riboflavina 0,1%)
Ophthalmic solution for parasurgical use

VEGA

Package
1 sterile pre-filled monodose dispenser

1 sterile single-use cannula needle

RICROLIN® is an ophthalmic solution containing Riboflavin 0.1%. This solution is instilled in the eye during irradiation of UV-A light as part of the parasurgical procedure of corneal collagen cross-linking. The principal objective of **RICROLIN®** is to provide a barrier against UV-A penetration beneath the corneal stroma, and thus protect the delicate internal structures of the eye (corneal endothelium, lens and retina) from damage that may be caused by radiation. **RICROLIN®** solution is in fact capable of reducing up to 95% of the UV energy that reaches the deep strata of the cornea.

Indications
In association with ophthalmic UV-A radiation, the solution is administered during conservative parasurgical procedures for keratoconus and other corneal estasia pathologies.
In particular the treatment is indicated in the following conditions:
- Diagnosed Keratoconus and/or secondary ectasia on the basis of clinical, topographical and pachymetrical analyses
- Clinically and instrumentally diagnosed Progressive Keratoconus
The administration of **RICROLIN®** in association with UV-A light retards the progression of Keratoconus.
This treatment can prevent the necessity of corneal transplant.
This treatment does not exclude the possible need of keratoplasty in the future.

Instructions for use
10-15 minutes prior to irradiation, instil 1 or 2 drops of the product using the appropriate dispenser provided and repeat treatment every 5 minutes. During treatment with UV-A light instil 1 or 2 drops of the solution every 5 minutes for a total of 30 minutes.

Composition
100ml of solution contains:
Riboflavin phosphate 0.127 g (equivalent to 0.1g of basic Riboflavin); Destrane T500 20g
Excipients: Bihydrate sodium phosphate monobasic, Bihydrate sodium phosphate bibasic, Sodium chloride, Distilled water q.b. for 100g

Contraindications
There are no known contraindications associated with the ophthalmic solution. Use must be avoided in cases of hypersensitivity reactions to the components of the product or to other chemically-related substances

Side Effects
No systemic or eye structure related side-effects have been reported

Precautions
- The product must be kept away from direct light
- Right up to the moment the product is to be utilised, it must be stored under refrigeration at a temperature between +4 and +8°C
- Kept within its dispenser, the solution is maintained sterile
- Do not touch the eye surface or other objects with the cannula needle in order to avoid the risk of contamination to the solution
- Do not utilise the product after more than one hour from first use
- Do not utilise the dispenser for more than one patient
- Do not utilise the product after the date indicated on the package
- Do not keep the product in temperature over 25°C
- The product is strictly indicated for external ophthalmic parasurgical use and is therefore utilised exclusively by registered Ophthalomologists.
- Do not utilise product if packaging is damaged

Package
1 monodose sterile dispenser filled with 1 ml solution
1 sterile single-use cannula needle

TECHNICAL CHARACTERISTICS

- Timer and Monitor to observe all procedure steps
- Control pedal
- Fixation point
- Incorporated telecamera with focus controller
- Improved irradiation consistency thanks to the excellent UV illuminator, integrated with innovative optical system
- Adjustable diaphragm to vary the treatment area
- Built on a stand with wheeled base
- Balanced operating arm

Characteristic of UVC source	Single LED for UV-A rays Maximum wavelength: 370nm Width of ray: 8nm
Power density of irradiation	3mW/cm2 (nominal) Accuracy: ± 10%
Diameter of radiated area	Between 4 -11 mm (@ 54mm)
Collimation system	Couple of red LED
Telecamera	Integrated with optic head Colour micro-telecamera
Monitor	Colour, 5.6 inch
Dimensions	1000 x 545 x 1280 mm

Bibliography
Aldo Caporossi, Cosimo Mazzotta e Stefano Baiocchi:
Principi, indicazioni, tecnica e risultati del Cross-Linking corneale Riboflavina + UV-A nella terapia del cheratocono evolutivo, editore I.N.C.

Aldo Caporossi MD, FRCS, Cosimo Mazzotta MD, PhD, Stefano Baiocchi MD, PhD:
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SOOFT group