LUMINA® / LUMINA®-Y

Acrylic Presbyopia Correcting Intraocular Lens (IOL)

Models:
LUMINA® (REF: AL00001)
LUMINA®-Y (REF: ALY0001)

Instructions for Use

Description
LUMINA® and LUMINA®-Y are two-element, foldable presbyopia correcting intraocular lenses (IOL) made of hydrophilic acrylic polymer. They are manufactured individually for a single eye to be implanted into the ciliary sulcus after removal of the natural lens (e.g. by phacoemulsification) in order treat aphakia and presbyopia. The LUMINA® contains a filter to reduce ultraviolet radiation, the LUMINA ®-Y provides an additional filter for reduction of blue light hazard (Figure 1). The IOL includes two optical elements providing a fixed optical power to correct refraction of the aphakic eye. In addition, the two elements provide a variable optical power for the presbyopia correcting function of the IOL, when shifted in a direction perpendicular to the optical axis. The haptic elements carrying elastic connections between the optical elements get in touch with the ciliary muscle of the eye and transfer forces for the lens power adjustment. The IOL is implanted such that its flanges are positioned in the plane of the ciliary sulcus. The IOL is made-to-order based on sulcus diameter and on required refractive power and asphericity of the individual eye.

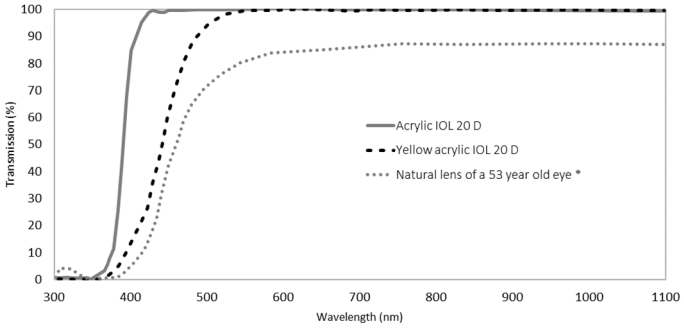

Figure 1: Spectral transmission of hydrophilic acrylic lenses
10% cut-off-wavelength ≥365 nm
**Source: Boettner, E.A. and Wolter J.R. Transmission of Ocular Media, Investigative Ophthalmology, 1962; 1:776-783*

The implanting surgeon should be experienced with the handling of foldable lenses and the implantation into the ciliary sulcus. Individual training on the application of the product is provided by the medical device specialists of the manufacturer.

Material
Hydrophilic acrylic copolymer from Hydroxyethylmethacrylate (HEMA) and Methylmethacrylate (MMA), water content: 26%, refractive index 1.46, Nd:YAG laser compatible. UV-absorber and blue light filter (LUMINA ®-Y only) are bound chemically.

Indication
The IOLs are indicated to correct aphakia and presbyopia in adults, in which the natural lens has been removed by extracapsular extraction. The IOLs are customized to the eye in optical power and size. The IOL is intended for the implantation into the ciliary sulcus of the aphakic eye.

Contraindications
In case of the following circumstances, an implantation should only be considered after thorough benefit-risk-analysis by the ophthalmologist:
- existing ocular diseases (e.g. severe chronic uveitis, proliferative diabetic retinopathy, untreated or non-treatable chronic glaucoma)
- corneal endothelial dystrophies
- vitreous loss
- microphthalmia
- rubeosis iridis
- severe iris atrophy
- suspected microbial infections
- rubella cataract
- risk of affection of observation, diagnosis or treatment of posterior segment diseases by the IOL
- preexisting factors negatively affecting the stability of the IOL in the eye (e.g. trauma, developmental ocular deformations, insufficient capsular bag stability or zonula weakness)
- challenging cataract extraction causing an elevated risk for complications (e.g. persisting hemorrhage, severe iris damage, uncontrollable elevation of intraocular pressure, vitreous prolapse, non-dilating pupil or vitreous loss)
- circumstances leading to an intraoperative damage to the corneal endothelium
- capsular bag or zonula defects leading to inadequate capsular bag support (e.g. requiring additional fixation of the IOL)
- corneal astigmatism > 1 D

Adverse Events
Possible complications include: Endothelial damage, retinal detachment, cystoid macula edema, elevated intraocular pressure (or secondary glaucoma), non-pigmentary precipitates, pupillary block, pupil ovalization, pupillary membrane, inflammations, synechiae, iris prolapse, corneal edema, keratopathy, hypotonia, vitreous loss, insufficient contraction of the posterior capsule, and any other undesired incidence leading to a permanent visual impairment or requiring surgical or medical intervention to prevent such permanent visual impairment.
LUMINA®/ LUMINA®-Y specific risks: wrong size or inversion in the eye, undesired refractive outcome, iris push by the IOL haptic – evaluation and correction during surgery

Clinical data / Clinical studies
The LUMINA® and LUMINA®-Y are advanced models of the single piece hydrophilic intraocular lenses intended for implantation into ciliary sulcus [1]. The clinical benefit of presbyopia correction has been demonstrated by a previous model of the LUMINA® IOL [2,3]. The manufacturer performs post market follow up investigations in order to increase the data basis on the clinical benefits.

IOL Calculation
The IOL is being calculated individually for each eye. For this, anterior segment optical coherence tomography and ocular path lengths (biometry) and the required power of a standard IOL calculated by an established IOL-calculator have to be transmitted to the manufacturer with the order form.

Handling
Before implantation of the IOL, the patient identification and date of expiry must be checked according to the packaging label. The lens must not be used for implantation after the date of expiry.
The integrity of the sterile barrier system (sterile pouch) must be checked before use. Sterility can only be guaranteed with an intact sterile pouch. The IOL container must be opened in sterile environment only.
The IOL must be warmed to a temperature between 18°C (operating room) and 36°C (eye) in order to prevent the IOL from damage during implantation. Open the screw cap and remove the sealing cap and lens case in order to take out the IOL from the container. The lens is located in the lens case and is then prepared for implantation. To do this, remove the spacer between the optics of the lens by pulling it out with sterile forceps. Then, check the lens surface for integrity and absence of particles.
To properly identify the anterior surface of the lens, make sure that the small fenestration window with the indicator nose is on the top of the lens and the indicator nose is left to the middle axis when following the middle axis from the optic center to the haptic.
Caution: The IOL must not dehydrate! Hydrophilic acrylic IOLs may only be wetted with isotonic salt solution or sterile water.
Caution: The IOL is stored in sterile water (WFI). Wait for state of equilibrium before measuring in isotonic salt solution.

Implantation
- The diameter of the capsulorhexis should be 0.5 mm smaller than the optic diameter of the IOL
- The anterior chamber should be filled with enough viscoelastic substance to ensure gentle implantation of the IOL.
- During implantation, the correct anterior/posterior alignment must be observed. The IOL is placed correctly, if the nose in the small fenestration is on the upper right or lower left of the horizontal axis (Figure 2).
- The foldable IOLs are suitable for implantation by forceps or injector system. The manufacturer has approved the following injector systems:
  - for the diopter range 10.0 to 24.0: AccuJect 2.2-1P (Medicel AG),
  - for the diopter range 10.0 to 30.0: AccuJect 2.6-1P (Medicel AG).
- When using injector systems for implantation, pay attention to the Instructions For Use of these injector systems.
- The IOL should preferably be implanted in the direction of the sulcus measurement, which is usually the horizontal axis (0° to 180°)
- Correct alignment of the IOL must be checked again after removal of the viscoelastic solution.
- Rinsing should also be performed between the optical elements to remove any viscoelastic material that may have penetrated.
- Ensure separation of the optical elements by surgical tools.
- Ensure that pupil is not trapped between optical elements or haptics and sclera.

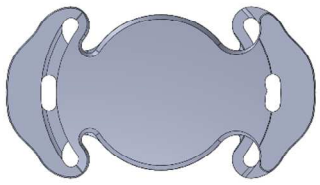

Figure 2: Front view of the lens showing the nose in the small fenestration at 3 o'clock position.

Warnings
A potential repositioning should, whenever possible, performed in any case before completion of capsular bag shrinkage within 1 to 2 weeks after implantation.
Due to the hydrophilic properties of the acrylic material, the IOL may absorb disinfectants, antibiotics or viscoelastic substances. This may result in a toxic lens syndrome. Therefore, careful irrigation and aspiration is mandatory at the end of surgery. Furthermore, can any dyes used during surgery (e.g. trypan blue) lead to a reversible coloration of the IOL.
Multifactorial effects can lead to postoperative changes to the IOL surface (e.g. elevated calcium and/or phosphate concentration due to distorted blood aqueous humor barrier).

MR Compatibility
The implant is made from biocompatible polymer material. A compatibility with MRI can be assumed. However, experimental data on the IOL models LUMINA® and LUMINA®-Y are not available. Tests with similar IOLs did not show an increase in temperature, image artifacts or misalignment. These tests were performed at 7 Tesla.

Reprocessing
Reprocessing/re-sterilization of the implant is strictly prohibited. For example, changes in the material could have serious consequences, including loss of the eye or death of the patient.

Disclaimer
The manufacturer is not liable for the implantation method used by the surgeon nor for the selection of the IOL in respect of the patient or his/her condition.

References

1. Prager F, Amon M, Wiesinger J, Wetzel B, Kahraman G. Capsular bag-fixated and ciliary sulcus-fixated intraocular lens centration after supplementary intraocular lens implantation in the same eye. J Cataract Refract Surg. 2017 May;43(5):643-647. doi: 10.1016/j.jcrs.2017.01.020. PMID: 28602326.
2. Alió JL, Simonov AN, Romero D, Angelov A, Angelov Y, van Lawick W, Rombach MC. Analysis of Accommodative Performance of a New Accommodative Intraocular Lens. J Refract Surg. 2018;34(2):78-83. Erratum in: J Refract Surg. 2018;34(3):216.
3. Alio JL, Simonov A, Plaza-Puche AB, Angelov A, Angelov Y, van Lawick W, Rombach M. Visual Outcomes and Accommodative Response of the Lumina Accommodative Intraocular Lens. Am J Ophthalmol. 2016;164:37-48.

Symbols and Explanations

SN	Serial number
REF	Reference number
$Ø_T$	Overall diameter
$Ø_B$	Optic diameter
STERILE	Sterilized using steam
	Use-by date (Year-Month)
	Do not reuse
	Do not resterilize
	No not use if packaging is damaged
	Keep away from sunlight
	Keep dry
	Temperature limit for storage
	Consult Instructions for Use
	Manufacturer
	Date of manufacture

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