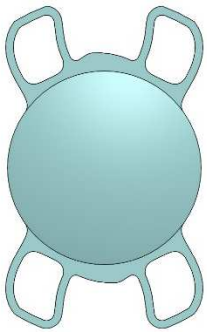
AMILens®Individual & AMILens®Individual-Y

Intraocular lens customized for an individual eye

Models:
AMILens®Individual (REF: IL01101)
AMILens®Individual-Y (REF: ILY1101)



Instructions for Use

Description
AMILens®Individual and AMILens®Individual-Y are single-piece, foldable, monofocal, toric intraocular lenses (IOL) with 4-loop haptics made of hydrophilic acrylic polymer. They are manufactured individually for a single eye to be implanted into the capsular bag after removal of the natural lens (e.g. by phacoemulsification) in order to restore the function of the natural lens. The AMILens®Individual contains a filter to reduce ultraviolet radiation, the AMILens®Individual-Y provides an additional filter for reduction of blue light hazard (Figure 1).

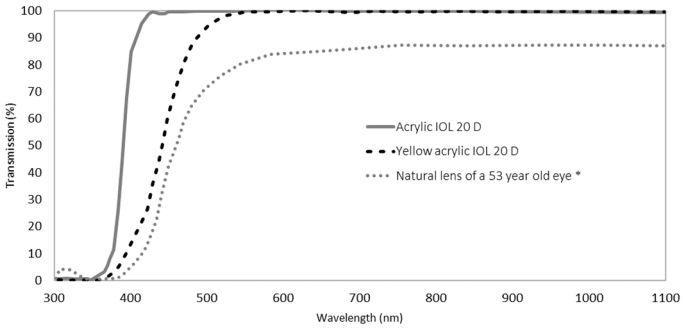


Figure 1: Spectal transmission of hydrophilic acrylic lenses
10% cut-off-wavelength ≥365 nm
**Source: Boettner, E.A. and Wolter J.R. Transmission of Ocular Media, Investigative Ophthalmology, 1962; 1:776-783*

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 (AMILens®Individual-Y only) are bound chemically.

Indication
The IOLs are indicated to correct aphakia in adults, in which the natural lens has been removed by extracapsular extraction. The IOLs are customized to the eye, to facilitate correction of corneal aberrations up to the 6th order such as astigmatism and/or spherical aberration. The IOLs are intended for implantation into the capsular bag.

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
- 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 or vitreous loss)
- circumstances leading to an intraoperative damage to the corneal endothelium
- capsular bag or zonula defects leading to inadequate capsular bag support

Adverse Events
Possible complications include: endothelial damage, retinal detachment, cystoid macula edema, elevated intraocular pressure or secondary glaucoma, non-pigmentary precipitates, pupillary membrane, inflammations, synechiae, iris prolapse, corneal edema, keratopathy, hypotonia, vitreous loss, insufficient adhesion 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.

Clinical data / Clinical studies
The aforementioned IOLs are enhancements of common IOLs with 4 haptics, which have been marketed by various manufacturers for many years. The AMILENS®-Individual and AMILENS®Individual-Y differ from the latter by customizing the optic to an individual eye to facilitate correction of existing corneal aberrations. The clinical benefit of individual correction of corneal aberrations has been demonstrated by improved contrast sensitivity and improved visual acuity [1-4]. 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, corneal tomography and ocular path lengths and the required power of the IOL calculated by an established IOL-calculator have to be transmitted to the manufacturer with the order form.

Handling
Due to the customization of the IOL, the delivery note and/or labels on the shipping package has to be checked, whether the lens is supposed to correct corneal astigmatism. This feature is visible in the specification of optical power in terms of sphere and cylinder. An IOL without correction of corneal astigmatism is identified with „0 D" cylinder power. If the cylinder is evident of being > 0 D, then the surgical preparation has to follow the rules for toric lens implantation – as described in the subsequent section:
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. Remove the screw cap and the plug to remove the IOL holder from the container. Open the cap of the lens holder to carefully take out the IOL with clean and sterile forceps. After removal of the IOL from the container, the lens surface must be checked if it is free from particles and damage.
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. Wait for state of equilibrium before measuring in isotonic salt solution.

Preparation of a patient for implantation of a toric IOL (with axis marker)
Note: This section is only valid for IOLs with toric power > 0 D. The horizontal (0°) or vertical (90°) axis of the cornea has to marked as reference axis. The patient should be sitting in an upright position when performing the axis marking to prevent the eyeball from rotating and to ensure correct marker position. The steep corneal axis should then be marked subsequently referring to the reference axis (0° or 90°)

Implantation
- The diameter of the capsulorhexis should be 0.5 mm smaller than the optic diameter of the IOL
- The anterior chamber and capsular bag should be filled with sufficient amount of 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 connecting line between the two opposite notches are located on the upper left and lower right (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 SE -20.0 to ≤ 25.0: AccuJect 1.8-1P (Medicel AG),
  - for the diopter range SE ≥ 25.0 to 60.0: AccuJect 2.0-1P (Medicel AG).
- When using injector systems for implantation, pay attention to the Instructions For Use of these injector systems.
- IOLs with markers at the rim of the optic
  - For correction of corneal astigmatism, the axis marker (Figure 2) of the IOL (flat axis) must be rotated to the steep corneal axis.
  - Rotating the IOL to align the axis marker to the steep corneal axis can be achieved by rotating the IOL clockwise with a push-pull-hook at the haptic-optic-transition.
- Correct alignment of the IOL must be checked again after removal of the viscoelastic device.

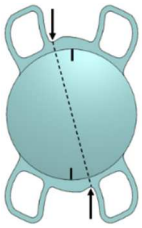


Figure 2: Front view of the lens showing the notches in correct position and the axis markers at 90°

Warning
Malrotation of an IOL with cylinder power can limit the correction of corneal astigmatism, eliminate or double the resulting astigmatism, so a repositioning should be considered. A malrotation of more than 30° can increase the resulting astigmatism. 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 AMILENS®Individual and AMILENS®Individual-Y are not yet 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. Jia L-X, Li Z-H. Clinical study of customized aspherical intraocular lens implants. Int J Ophthalmol. 2014;7(5):816–821.
2. Schrecker J, Langenbucher A, Seitz B, Eppig T. First results with a new intraocular lens design for the individual correction of spherical aberration. J Cataract Refract Surg. October 2018;44(10):1211–1219.
3. Schrecker J, Schröder S, Langenbucher A, Seitz B, Eppig T. Individually Customized IOL Versus Standard Spherical Aberration-Correcting IOL. J Refract Surg. September 2019;35(9):565–574.
4. Tan Q-Q, Lin J, Tian J, Liao X, Lan C-J. Objective optical quality in eyes with customized selection of aspheric intraocular lens implantation. BMC Ophthalmology. July 2019;19(1):152.

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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