AMILens®Phakic

Intraocular lens manufactured for an individual eye

Model:
AMILens®Phakic (REF: PL00001)

Orientation for the right eye (OD)

Orientation for the left eye (OS)

Instructions For Use

Description
The AMILens®Phakic is a foldable monofocal, toric posterior chamber intraocular lens with plate haptics intended for implantation into the ciliary sulcus of a phakic eye. The overall diameter of the lens is available from 10.0 to 13.0 mm in steps of 0.05 mm to facilitate an exact fit into the ciliary sulcus.

All surgeons must have completed the AMILENS®Phakic Training prior to use.

Material
Hydrophilic acrylic copolymer from Hydroxyethylmethacrylate (HEMA) and Methylmethacrylate (MMA), water content: 26%, refractive index 1.46, with chemically bound UV-absorber.

Indication
The IOL is indicated for the correction of medium and high ametropia and astigmatism in adults between 21 and approx.. 45 years of age. The IOL is intended to correct myopia between -1 D and -30 D, hyperopia between +1 D and +8 D and astigmatism of up to 6 D (steep meridian between -30 D and +8 D at spectacle plane).

Contraindications
In case of the following circumstances, an implantation should only be considered after thorough benefit-risk-analysis by the ophthalmologist:
- endothelial cell density < 2000 cells/mm²
- anterior chamber depth < 2.8 mm (measured from endothelium to anterior lens capsule)corneal endothelial dystrophies
- vitreous loss
- keratoconus
- situation after keratoplasty
- existing ocular diseases (e.g. severe chronic uveitis, proliferative diabetic retinopathy, untreated or non-treatable chronic glaucoma)
- cataract / non-traumatic cataract in the fellow eye
- congenital cataract / rubella cataract
- narrow anterior chamber angle (smaller than grade III according to gonioscopic assessment)
- microphthalmus
- rubeosis iridis
- severe iris atrophy
- suspected infection (viral, bacterial, or fungal)
- risk of impairment of examination, diagnosis or treatment of posterior segment diseases
- preexisting factors negatively affecting the stability of the IOL in the eye (e.g. previous ocular trauma, developmental disorder, or zonula weakness)
- large iris defects
- circumstances leading to an intraoperative damage to the corneal endothelium
- any ocular disease limiting the expected visual acuity to 0.3 or less
- decimal pregnancy or breast feeding
- implantation in the functionally only eye (except if the patient has been advised about the risk of complete blindness)

Special attention and at least yearly follow-up examinations are indicated under the following circumstances:
- non-stable refractive errors
- synechiae
- anamnestic iritis/uveitis
- pigment dispersion syndrome
- pseudoexfoliation
- insulin-dependent diabetes mellitus
- diabetic retinopathy
- history of previous ocular surgery, especially corneal refractive surgery

Potential complications
Cataract can be induced when the lens is in contact with the natural lens. A too large overall diameter of the IOL may lead to lens vaulting and narrowing of the anterior chamber angle with increasing intraocular pressure. Performing an iridotomy preoperatively can counteract the risk of vaulting and narrowing of the anterior chamber angle (see section "Preparation of a patient"). A too small IOL may lead to iris chafing and pigment release. Therefore, the diameter of the ciliary sulcus must be measured prior to ordering and implantation of the lens. An exchange of the lens should be considered in cases of persisting excessive vaulting or iris chafing and affection of the anterior chamber angle or increase of intraocular pressure.
In addition, the following intra- and postoperative complications may occur:
Endothelial damage, retinal detachment, cystoid macula edema, elevated intraocular pressure (or secondary glaucoma), non-pigmentary precipitates, pupillary membrane, pupillary block, inflammations, synechiae, iris prolapse, corneal edema, keratopathy, hypotonia, cataract, vitreous loss, hemorrhage 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 IOL is a further development of an intraocular contact lens that has been marketed by various manufacturers for many years [1-4]. The AMILens®Phakic differs from these established IOLs in its individually for the eye manufactured optic and total diameter to allow individual compensation for spherical aberration and secure optimized anatomical fit to the eye.
The manufacturer also conducts post-market follow-up studies in order to put the clinical benefits of these IOLs on a broader database.

IOL calculation
The IOL is calculated by the manufacturer on an individual basis. For this purpose the manifest refraction, partial optical lengths and optical aberrations as well as the diameter of the ciliary sulcus will be transmitted to the manufacturer.

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 rinsed and checked if it is free from particles and damage. When folding the IOL with a cartridge-injector system the IOL may show grooves. These are caused by the short-term high pressure squeezing water out of the material. This process is reversible and an IOL showing these grooves after surgery should not be explanted.
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
It is recommended to carry out YAG iridotomies superiorly and inferiorly 1-2 weeks before the planned implantation of the AMILens®Phakic. The patency of the iridotomies must be confirmed prior to lens implantation.

Preparation 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°) 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.

Implantation
- The IOL must be implanted into the ciliary sulcus so that the concave side faces the natural lens.
- Contact of the IOL with the natural lens must be avoided
- The foldable IOLs are suitable for implantation by forceps or injector system. For the implantation with injector systems the manufacturer has approved the injector system AccuJect 2.0-1P (Medicel AG).
- When using injector systems for implantation, pay attention to the Instructions For Use of these injector systems.
- The IOL should always be implanted in horizontal position (from 9 to 3 o'clock). The astigmatic axis is encoded in the lens, therefore also toric models are to be implanted horizontally.
- For horizontal positioning the IOL has an alignment-mark on each side along the 0°/180°-axis.
- IOLs with cylinder power have additional marks (each side three dot-markings) along the lower refractive main-axis (plus cylinder axis).
- The following applies to the orientation of the openings of the haptics:
  Right eye (OD): The circular openings of the haptics should be on the upper left and lower right.
  Left eye (OS): The circular openings of the haptics should be on the lower left and upper right.

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.
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).

Postoperative examination
The intraocular pressure must be observed after 24 hours postoperatively for any spikes in pressure or persisting increase of intraocular pressure. The long term effects of this lens have not been investigated so far, therefore at least yearly follow-up examinations are recommended.

MR Compatibility
The implant is made from biocompatible polymer material. A compatibility with MRI can be assumed. However, experimental data on the IOL model AMILENS®Phakic 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. Bredow L, Biermann J, Tomalla M, Schilgen G, Grossmann W, Reinhard T. Pilot study of a new posterior chamber phakic intraocular lens (epi.lens) for high myopia. J Refract Surg. 2011;27(12):858-62.
2. Gasser L, Biermann J, Reinhard T. New posterior chamber phakic intraocular lens for high myopia: three-year results. J Cataract Refract Surg. 2015;41(8):1610-5.
3. Igarashi A, Shimizu K, Kamiya K. Eight-year follow-up of posterior chamber phakic intraocular lens implantation for moderate to high myopia. Am J Ophthalmol. 2014;157(3):532-9.e1.
4. Alfonso JF, Baamonde B, Fernández-Vega L, Fernandes P, González-Méijome JM, Montés-Micó R. Posterior chamber collagen copolymer phakic intraocular lenses to correct myopia: five-year follow-up. J Cataract Refract Surg. 2011;37(5):873-80.

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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Version: V03.2 / 2023-11