HumanOptics

en

Instructions for use

Acrylic Intraocular Lens

These instructions for use are for the following intraocular lenses (abbreviated "IOLs"):

Model overview and performance characteristics:

MODEL	DESIGN	DIOPTER RANGE	Basic UDI-DI
Monofocal			
Aspira-aA/-aAY	aspheric, aberration-free, posterior surface with 360° lens epithelial cell barrier	-20.0 D – 60.0 D	04049154_PC_M2_H2_O2_BU
Aspira-aXA/-aXAY		-10.0 D – 30.0 D	04049154_PC_M2_H4_O2_CJ
Aspira-aA+/-aAY+	adjusted aspheric, posterior surface with 360° lens epithelial cell barrier	0.0 D – 30.0 D	04049154_PC_M2_H2_O2_BU
Monofocal toric			
Torica-aA/-aAY	aspheric, aberration-free, toric, posterior surface with 360° lens epithelial cell barrier	-20.0 D – 60.0 D (SE) Cyl 1.0 D – 20.0 D	04049154_PC_M2_H2_O3_BX
Multifocal			
Triva-aA/-aAY	aspheric, aberration-free, multifocal (trifocal) diffractive, posterior surface with 360° lens epithelial cell barrier, intermediate addition +1.75 D and near addition +3.5 D	10.0 D – 30.0 D	04049154_PC_M2_H2_O4_C2
Triva-aXA/-aXAY			04049154_PC_M2_H4_O4_CQ
Multifocal toric			
Triva*T*-aA/-aAY	aspheric, aberration-free, toric, multifocal (trifocal) diffractive, posterior surface with 360° lens epithelial cell barrier, intermediate addition +1.75 D and near addition +3.5 D	10.0 D – 30.0 D (SE) Cyl 1.0 D – 6.0 D	04049154_PC_M2_H2_O5_C5

Note: Not all models and diopter ranges are available for sales in all countries.

Fig. 1: Technical drawing of the different types of IOL models with monofocal optic as an example (left: C-Loop models with the ending -aA/-aAY and -aA+/-aAY+, right: Cut-out haptic models with the ending -aXA/-aXAY)

1. Description

A sterile (sterilized using steam), foldable, one-piece, UV-absorbing hydrophilic acrylic posterior chamber IOL with 0° haptic angulation in isotonic saline solution for implantation into the capsular bag after emulsification of the natural lens. The models labelled with "Y" additionally contain a blue-light filter.

All models with the ending -aA/-aAY and -aA+/-aAY+ are designed with C-loop haptics, an overall diameter of 12.5 mm and a body diameter of 6.0 mm. All models with the ending -aXA/-aXAY have cut-out haptics, an overall diameter of 11.0 mm and a body diameter of 7.0 mm.

For further information regarding the specification of the IOLs listed in the table above, please visit www.humanoptics.com.

There are two different packaging versions. Not all products are available in both versions:

a) Compact line: The IOL is packaged in a flat container for manual loading into a conventional cartridge injector.

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b) SAFELOADER®: The SAFELOADER® Autoloading System is composed of an ACCUJECT™ injector with integrated cartridge (manufacturer: Medicel AG) and an autoloading container with a preloaded acrylic IOL. The injector is not part of the SAFELOADER® packaging and is supplied in a separate packaging.

All parts are single-use components.

A list of suitable injection systems can be found under www.humanoptics.com.

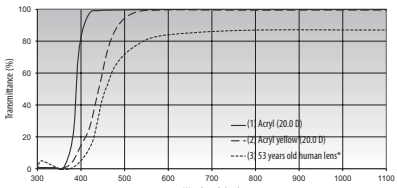

Fig. 2: Transmittance spectra of the hydrophilic acrylic IOLs 10% cut-off wavelength:
Curve (1): the cut-off wavelength at 10% transmission is 375 nm
Curve (2): the cut-off wavelength at 10% transmission is 380 nm
* Source: Boettner E.A., Wolter J.R. Transmission of Ocular Media, Investigative Ophthalmology, 1962; 1:776–783

2. Mode of action / operating principle

All IOLs covered by these instructions replace the crystalline lens after surgical removal of the natural lens and are designed to focus light passing through the cornea and pupil onto the retina, like the eye's natural lens.

All models with ending -aA/-aAY/-aXA/-aXAY have an aspheric optic design, which is aberration-free (spherical aberration). The models with ending -aA+/-aAY+ have an adjusted aspheric optic.

Monofocal IOLs provide clear vision at one focal point (usually far focus).

The models with the ending -aXA/-aXAY are designed with a large optic of 7 mm to prevent incoming light to scatter at the edge of the lens optic, thereby minimizing photopic phenomena.

Multifocal IOLs contain a hybrid optic which combines a central diffractive zone with gradual tapering and a peripheral refractive zone in order to create three (Triva) focal points. Thereby visual acuity at near (addition +3.5 D at IOL plane), intermediate (addition +1.75 D at IOL plane) and far distance is restored, which counteracts pseudophakic presbyopia.

Toric IOLs correct corneal astigmatism. Therefore, the IOL meridians of strongest and of weakest refraction are aligned opposite to those of the astigmatic cornea during implantation.

Multifocal toric IOLs combine the principles of multifocal and toric lenses.

All yellow IOLs (Y) contain a blue light filter that absorbs the high-energy portion of the blue short-wave light.

3. Material

The material is an optically clear, biocompatible, foldable, hydrophilic acrylic copolymer consisting of polyacrylate (74%) with saline solution (26%), with a refractive index of 1.46 and an Abbe number of 56 and it is also Nd:YAG laser-compatible.

The polyacrylate consists of the main components 2-hydroxyethyl methacrylate (HEMA, approx. 80%) and methyl methacrylate (MMA, approx. 20%) with a UV absorber (< 1%).

Models named with an additional 'Y' contain additionally a blue light filter (< 0.05%) to absorb the high-energy component of the blue light.

Preclinical tests conducted according to applicable international standards confirmed that the IOL material is stable and that no safety-relevant quantities of substances are released.

4. Intended purpose

4a. Indications

All IOLs covered by these instructions for use are indicated for the correction of aphakia after surgical removal of the natural lens. In addition, toric IOLs are indicated to correct pre-existing regular, stable corneal astigmatism.

Multifocal IOLs are indicated for patients who desire near, and/or intermediate, and distance vision with increased spectacle independence. However, accommodation will not be restored. Toric-multifocal IOLs can further correct pre-existing regular, stable corneal astigmatism.

4b. Intended purpose / intended use

All these IOLs are intended for implantation in the capsular bag to replace the natural lens.

4c. Intended patient population

Aphakic adult patients.

Notes: children are excluded due to the absence of clinical data and additional risks associated with paediatric cataract surgery.

The manufacturer does not hold clinical data relating to pregnant/breastfeeding women or immuno-compromised patient populations.

4d. Intended users

IOLs must be handled by health professionals and implanted by ophthalmic surgeons.

4e. Contraindications

Outside of general contraindications of ocular surgery, there are no specific contraindications for the IOLs covered by these instructions.

5. Caution

Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions:

- Uveitis
- Proliferative diabetic retinopathy
- Uncontrolled chronic glaucoma
- Corneal endothelial dystrophy
- Microphthalmos or macrophthalmos
- Suspected ocular infection
- Extreme myopia (ocular axial length > 30.0 mm) may be a risk factor for IOL capsule inadhesion that may impact negatively visual acuity
- Pre-existing ocular conditions which may negatively impact the stability of the implanted IOL (e.g. distorted eye due to previous trauma or developmental disorder, instability of the posterior capsule/zonules)
- Surgical difficulties at the time of cataract extraction which might increase the risk for complications (e.g. persistent bleeding, significant iris damage, uncontrolled IOP elevation, significant vitreous prolapse or loss)
- Circumstances that would result in damaging the endothelium during implantation

For multifocal IOLs, caution should also be exercised in the following conditions:

- Amblyopia
- Optic nerve atrophy
- Significant corneal aberrations
- Medical conditions that may impair vision
- Eye anatomies or conditions (such as refractive treatments) that do not allow reliable prediction of postoperative refraction

6. Warnings

- Due to the hydrophilic properties of the material, substances such as disinfectants, antibiotics or viscoelastics can theoretically be absorbed by the lens. This may lead to a toxic lens syndrome. Therefore, at the end of surgery, care should be taken to remove all substances from the eye by using standard irrigation/aspiration techniques. Also be aware that dyes used intraoperatively (e.g. trypan blue) may cause staining of the IOL.
- Salt precipitation in/on the lens may occur in very rare cases when using exogenous material such as, but not limited to, add-on lens, air or gas during corneal surgery or vitrectomy. The mechanism and the incidence are to date not clear.

7. Special considerations prior to multifocal IOL implantation

- It is recommended to target emmetropia.
- Patients with significant preoperative astigmatism, determined by keratometry, or expected postoperative astigmatism > 0.5 D may not achieve optimal visual outcomes.
- In cases of corneal astigmatism > 1.0 D, implantation of a toric-multifocal IOL is recommended.
- Lens tilt and decentration may negatively affect the quality of vision.

8. Special considerations prior to toric IOL implantation

- The dioptric power of toric IOLs is indicated as "spherical equivalent (SE) and cylinder (cyl)". Please check the label carefully.
- Precise biometry, keratometry, topography/tomography and precise lens axis alignment relative to the intended axis are keys to a successful correction of astigmatism.
- Misalignment of the toric IOL relative to the intended axis can reduce or negate the refractive benefit, or even worsen the refraction. In such cases, lens repositioning should be considered and should take place within the first two weeks after surgery, prior to IOL encapsulation (shrinking).
- Eyes with an axial length > 24.0 mm are more at risk of post-surgery IOL rotation.
- If possible, posterior corneal astigmatism (tomography) should be considered, especially with astigmatism < 2.0 D.

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9. Potential complications, undesirable side effects and residual risks

As with any surgical procedure, cataract surgery with IOL implantation presents risks, which the surgeon must evaluate. The surgeon is obliged to inform the patient about the following potential complications and undesirable side effects in relation to the cataract surgery and lens implantation (the list does not claim to be exhaustive):

- Corneal endothelial decompensation, corneal edema, retinal detachment, cystoid macular edema, increased intraocular pressure, inflammation (e.g. toxic anterior segment syndrome, endophthalmitis, uveitis, iritis), iris trauma, posterior capsular and zonular rupture, secondary surgical intervention (e.g. repositioning, removal, or exchange), posterior capsule opacification (PCO), IOL decentration or tilt, deviation from target refraction.

Further points to note in connection with multifocal IOLs (Triva, Triva*T*):

- As with all multifocal IOLs, a reduction in contrast sensitivity as compared to a monofocal IOL may occur. This can be more prevalent in poor light conditions.
- Some visual effects may be experienced due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or rings around point sources of light under dark conditions. The perception of the visual phenomena usually decreases with time.

Further points to note in connection with toric IOLs:

- A postoperative rotation of the toric IOLs may reduce the astigmatism correction.
- Misalignment of the toric IOL relative to the intended axis can reduce or negate the refractive benefit, or even worsen the refraction. In such cases, lens repositioning should be considered and should take place within the first two weeks after surgery, prior to IOL encapsulation (shrinking).

10. Calculation of dioptric power

Accurate biometry is essential to successful visual outcomes. Preoperative calculation of required lens power for the IOL should be determined by the surgeon's experience, preference, and intended place. In this context, the incision location and the surgeon's estimated surgically induced corneal astigmatism should be considered, particularly in the case of toric IOLs. Lens constants must be "personalized" to address differences in instrumentation, measurements, and surgical techniques, and IOL power calculation methods. As a starting point for IOL power calculations, please use the constants for the respective formula and product as recommended by the manufacturer (www.humanoptics.com). The printed A-constant on the box is only an estimated value, which is not recommended for calculation of the dioptric power. Special care should be taken in the case of eyes with extreme dimensions (high myopia/hyperopia) and following prior refractive surgery, where determining the optimal lens power is particularly challenging. Physicians requiring additional information for dioptric power calculation should contact the manufacturer (application@humanoptics.com).

11. Clinical benefits

The primary clinical benefit of IOL implantation is the correction of aphakia after cataract surgery and prevention of blindness.

IOLs provide functional far vision and improve patients' quality of life and reduce their dependence on glasses for one distance (far vision).

Certain IOL models offer further clinical advantages:

- Triva IOLs provide functional intermediate and near vision.
  This counteracts pseudophakic presbyopia in patients who have had a cataractous or non-cataractous lens removed to achieve greater independence from glasses.
- Torica IOLs correct corneal astigmatism to achieve independence on glasses in one distance.
- Triva*T* IOLs combine the correction of corneal astigmatism with the benefits of restoring visual acuity in more than one distance.
- The models with the ending -aXA/-aXAY are designed with a large 7 mm optic to minimize interfering edge effects (dysphotopsia) due to the overlap of the pupil and IOL optic, which might be particularly relevant in case of large pupils. In addition, the 7 mm optic enables practitioners an extended view of the fundus during the surgery and at the postoperative visits, which may be of considerable value to assess the progression of retinal diseases.

12. Safety and clinical performance

For products registered under Regulation (EU) 2017/745, the summary of safety and clinical performance (SSCP) will be published in EUDAMED, the European Database on Medical Devices, under the URL www.ec.europa.eu/tools/eudamed. In EUDAMED, the SSCP is linked to the Basic UDI-DI of the product, which is listed on the front page of this document. Until EUDAMED will be fully functional, the SSCP is available at www.humanoptics.com.

Find HumanOptics Holding under the SRN DE-MF-000017892 on EUDAMED.

The SSCP is reviewed at least annually and updated if needed to ensure that any clinical and/or safety information in the SSCP remains correct and complete.

13. Handling

- Store the lens between 10°C / 50°F and 30°C / 86°F, protected from light and under dry conditions.
- Do not re-use the implant or any parts of the packaging.

- Before use, check the lens package for the correct lens model, dioptric power and expiration date. The lens should not be implanted after the indicated expiration date.
- Before use, check the integrity of the sterile barrier system. The IOL is sterile only if the sterile pouch is undamaged. The lens container may only be opened under sterile conditions. Only implant a sterile IOL.
- Before use, the IOL should be warmed to temperatures between 18°C / 64.40°F (operating room) and 36°C / 96.80°F (intraocular temperature) to avoid any risk of damage to the IOL during implantation.
- To remove the IOL, hold the flap of the sealed foil lid of the container and pull it off, then remove the protective cover (only Compact Line). After removing the IOL from the container, ensure that the IOL surface is free of any adhering particles or any other defects.
- For SAFELOADER® products, the integrity of the IOL must be checked after successful loading of the loading chamber.

Attention: The IOL should not dehydrate! Hydrophilic acrylic IOLs may only be wetted with sterile isotonic saline solution.

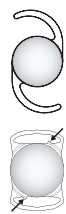
In the event of a malfunction of the device or a change in its performance, please return the affected product including all available documentation (e.g. labels, packaging) to your local distributor or the manufacturer. Please make sure to clearly mark contaminated material when returning it to the manufacturer. Contact to the manufacturer via email: complaint@humanoptics.com.

14. Preparation of the patient before implantation of toric IOLs

If manual marking is performed, please consider the following steps:

- With the patient sitting upright, mark the horizontal axis (0°) or the vertical axis (90°) on the cornea, as the reference axis. Positioning the patient in an upright sitting position is important to prevent ocular cyclotorsion.
- Then, mark the steepest axis or the implantation axis calculated taking into account the surgically induced astigmatism of the cornea using the reference axis (0° or 90°).

15. Implantation



- The capsulorhexis size should be about 0.5 mm smaller than the optic diameter of the IOL.
- To ensure smooth and safe IOL implantation, fill the anterior chamber and capsular bag with sufficient viscoelastic material.
- During implanting, ensure correct anterior/posterior orientation of the IOL: the extremities of the C-loop haptics point in a counterclockwise direction (anterior view). The models with other haptic geometries are correctly oriented when one marking appears on the top right and the other marking on the bottom left (see graphics).
- Implantation of the foldable acrylic IOLs can be performed using either forceps or an injection system. Please follow the instructions for use of the injector used before loading the IOL.
  - All IOLs of this instruction of use were tested with the injection system AccuJect™ from Medicel AG and are suitable for this application. A list of suitable injector sizes in relation to the optical power can be found under www.humanoptics.com.
  - When using a non-tested injector system for implantation, please refer to the specific instructions for use provided with the injector system to ensure that it is suitable to use with the IOL to be implanted.
  - When using SAFELOADER® products, please refer to the enclosed SAFELOADER® – Instruction for use.
  - The IOLs have to be implanted immediately after loading!
- Special recommendations for toric IOLs:
  - The axis of the plus cylinder (meridian of lowest dioptric power) is indicated by two opposite indentations (markings) at the edge of the optic. Correct the corneal astigmatism by aligning the markings of the IOL with the postoperative steep axis of the cornea.
  - In order to achieve the intended position, the IOL can be rotated (clockwise in the case of the C-loop) with a push-pull hook placed at the optic-haptic junction. It might be useful to position the IOL 10° to 20° shy of the desired position, remove the viscoelastic material, then rotate the IOL to its final position.
  - At the end of surgery, it is important to completely remove all viscoelastic material from behind the implant.
  - After removing the viscoelastic material, recheck the correct IOL positioning.
  - Patients should be kept at rest immediately after surgery in order to keep the IOL stable.

16. MRI safety status

The implant is MR Safe, and in MRI examinations it does not display any increase in temperature, image artifacts or changes in position. All tests to investigate MRI safety were performed at 7 Tesla.

17. Reprocessing

Reprocessing of the implant is strictly prohibited, since material changes, for example, may cause serious complications and can be fatal.

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18. Disposal in accordance with national and local regulations

Discarded IOLs (used or unused) are classified as medical or clinical waste due to their potentially infectious nature and must be disposed of in accordance with national and local regulations.

19. Patient information

The packaging of every product includes a patient card, which is to be given to the patient. Enter the patient data on the patient card and apply the self-adhesive label containing the product identification to the designated space on the card. Instruct the patient to keep this card as a permanent record and to show it to any eye care professional consulted in the future. For further patient information please visit www.humanoptics.com/patient-information.

20. Lifetime of the IOL

The IOLs are intended to remain permanently in the patient's eye. Simulated aging tests on the material confirm the stability of the intraocular lens over a product lifetime of twenty years. Due to the properties of the material, the devices are expected to be stable indefinitely from the implantation date over the lifetime of the patient. Regular ophthalmological check-ups are recommended, as for patients with natural lenses.

21. Reporting

Serious incidents and events should be reported to HumanOptics and to the relevant competent authorities.

22. Disclaimer

The manufacturer is not liable for the implantation method or the operative technique used by the physician performing the procedure or for the selection of the IOL in relation to the patient or his condition.
The IOLs are restricted to sale by or on the order of a physician or any other health entity.

23. Symbols and Explanations

SN	Serial number		Manufacturer
REF	Reference number	DE	Date of Manufacture and Country of Manufacture (DE)
$Ø_T$	Total diameter	MD	Medical device
$Ø_B$	Body diameter	MR	MR Safe
STERILE	Sterilized using steam	UDI	Unique Device Identifier
	Use-by date (YYYY-MM-DD)		Single sterile barrier system with protective packaging inside
	Do not re-use		Patient name or patient ID
	Do not resterilize	31	Date of implantation
	Do not use if package is damaged		Name and address of the implanting healthcare institution/provider
	Keep away from sunlight		Information website for patients
	Keep dry	OD	Right eye
10°C 30°C storage	Temperature limit for storage	OS	Left eye
	Consult instructions for use		

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V16.0/2025-04

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