Instructions for Use

- **PRODUCT NAME**
  Hydrophobic Acrylic Aspheric IOL

- **TRADE NAME**
  Eyenable ®

CE 2797

- **DESCRIPTION**

The Eyenable® Hydrophobic Acrylic Aspheric IOL (Model PA60ATT) is a foldable single-piece ultra-violet absorbing toric posterior chamber intraocular lens (henceforth, referred to as Eyenable® IOL/IOL). It is an optical implant to replace the human crystalline lens in the visual correction of aphakia and pre-existing corneal astigmatism in adult patients after cataract removal. The Eyenable® IOL is made of a high refractive index soft hydrophobic acrylic material.

Eyenable® IOL (Model PA60ATT) is designed with negative spherical aberration to reduce total spherical aberration in pseudophakia eye and supporting haptics to provide proper position of the IOL optic within the capsule. There are toric axis marks on the anterior surface of IOL to denote the flat meridian (plus cylinder axis). Alignment of the toric axis marks with the post-operative steep corneal meridian allows the lens to correct preexisting corneal astigmatism. The physical properties of the lens are shown in the Figure 1.

Figure 1: PHYSICAL CHARACTERISTICS of Eyenable® IOL
All dimensions in millimeters

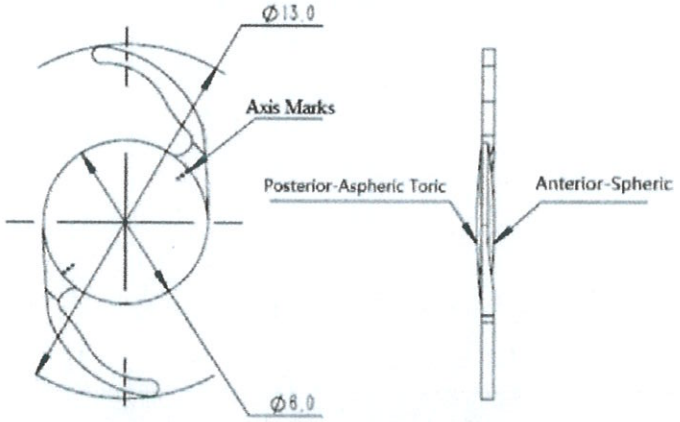
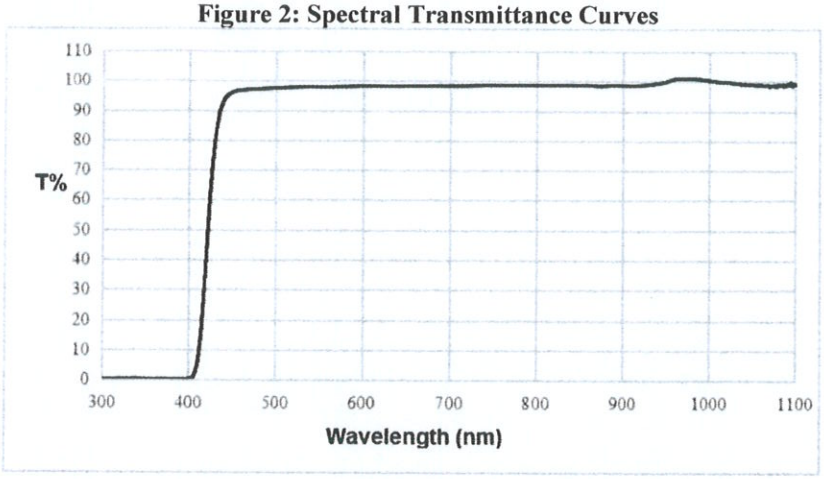


Table 1: Model Characteristics Chart

Items	*Description*							
Model	PA60ATT							
	PA60AT2	PA60AT3	PA60AT4	PA60AT5	PA60AT6	PA60AT7	PA60AT8	PA60AT9
IOL Cylinder Powers (D)	0.75	1.50	2.25	3.00	3.75	4.50	5.25	6.00
Optic Type	Anterior Spherical Surface and Posterior Aspherical Toric Surface							
Optic Material	Ultraviolet Absorbing Acrylate / Methacrylate Copolymer							
Spectral Transmission (in air)	10% transmittance at 413 nm (UV) for +20.0D increments							
Optical Powers (spherical equivalent diopters)	+6.0 ~ +34.0D +6.0 ~ +30.0 with 0.5D increment +31.0 ~ +34.0 with 1D increment							
Index Of Refraction	1.55 at 35℃							
Haptic Configuration	Modified-L Haptics							
Haptic Material	Ultraviolet Absorbing Acrylate / Methacrylate Copolymer							
Haptic Color	Clear							
Optic Diameter $Ø_B$ (mm)	6.0							
Overall Length $Ø_T$ (mm)	13.0							
Haptic Angle	0°							

Figure 2: Spectral Transmittance Curves



■ **NOTES:**

- The cutoff wavelength and the spectral transmittance curves presented here represent the transmittance values of the 20.0D Eyenable® IOLs made from hydrophobic acrylate with bonded UV-absorber.
- Measurements were by direct transmittance using Eyenable® IOLs with center thickness equivalent to the marketed range.

■ **INDICATIONS**

The Eyenable ® IOL (PA60ATT) is indicated for the replacement of the human lens to achieve visual correction of aphakia and pre-existing corneal astigmatism in adult patients when extracapsular cataract extraction or phacoemulsification are performed (see warning). The Lens is intended for placement in the capsular bag.

■ **INTENDED USE**

The Eyenable® IOL is intended for use by a trained ophthalmic surgeon. The IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia and pre-existing corneal astigmatism. The biconvex aspheric toric optic reduces spherical aberration as compared to a standard spherical toric optic in an average eye. There are toric axis marks on the anterior surface of IOL to denote the flat meridian (plus cylinder axis). Alignment of the toric axis marks with the post-operative steep corneal meridian allows the lens to correct preexisting corneal astigmatism. The astigmatic correction at the corneal plane for Eyenable ® IOL is shown in Table 2.

Table 2: Astigmatic Correction at the Corneal Plane for Eyenable® IOL Models

Model	Cylinder Power at IOL Plane (Diopters)	Cylinder Power at Corneal Plane (Diopters)*
PA60AT2	0.75	0.52
PA60AT3	1.50	1.04
PA60AT4	2.25	1.56
PA60AT5	3.00	2.08
PA60AT6	3.75	2.60
PA60AT7	4.50	3.12
PA60AT8	5.25	3.64
PA60AT9	6.00	4.17
***Based on an average pseudophakic human eye**		

■ **BIOCOMPATIBILITY TESTING**

Potential patient safety risks to the material(s) of this device were evaluated through nonclinical physicochemical characterization and biocompatibility testing in accordance with international standards applicable to IOL devices. Nonclinical testing demonstrated no safety concerns for local or systemic toxicity, that the IOL material was physically and optically stable, and that there were no leachable substances arising from the manufacturing process (including sterilization) or device material(s) that posed a safety risk. The device possesses an acceptable patient safety profile when used in accordance with the Directions for Use (DFU) for its intended clinical purpose as an ocular implant device.

■ **HOW SUPPLIED**

The Eyenable® IOL is supplied dry, in a package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions (see DIRECTION FOR USE).

■ **QUALIFIED COMBINATIONS FOR IOL IMPLANTATION**

During implantation of the Eyenable® IOL, a qualified delivery system and ophthalmic viscosurgical device (OVD) combination should be used. The use of an unqualified combination may cause damage to the lens and potential complications during the implantation process (e.g., IOL decentration, tilt, dislocation, spatial distortions, visual disturbances, or decreased/blurred vision, and etc.).

The Eyenable® IOL manufacture recommends the qualified combinations that can be used with this lens are listed in table below.

Model	Diopter range	Cartridge	OphthalmicViscosurgicalDevice (OVD)
PA60ATT	+6.0D to +34.0D	ACCUJECT/Dual≥2.2mm tip	Any OVD product already on the market

■ **CALCULATION OF LENS POWER**

Preoperative calculation of required lens power for these posterior chamber intraocular lenses should be determined by the surgeon's experience, preference, and intended lens placement. Lens power calculation methods are described in the following references:

(1) Hoffer, K.J. The Hoffer Q formula: A comparison of theoretic and regression formulas. J. Cataract Refract. Surg. 19:700-712, 1993.

(2) Holladay, J.T., et al. A three-part system for refining intraocular lens power calculations. J. Cataract Refract. Surg. 14:17-24, 1988.
(3) Holladay, J.T., et al., Standardizing constants for ultrasonic biometry, keratometry, and IOL power calculations, J. Cataract Refract. Surg. 23:1356-1370, 1997.
(4) Retzlaff, J.A., Sanders, D.R., and Kraff, M. Lens Implant Power Calculation, 3rd ed., Slack, Inc., Thorofare, N.J., 1990.

SUGGESTED A-CONSTANT

The suggested A-constant listed on the outer label is presented as a guideline and is a starting point for implant power calculations. It is recommended that you develop your own constant appropriate for you based on clinical experience with the particular lens models, surgical techniques, measuring equipment, and postoperative results.

CONTRAINDICATIONS

There are no known contraindications with the use of Eyenable® IOL when used as recommended.

CAUTION

Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient's eyesight. Patients with preexisting conditions may not achieve the visual acuity as of patients without such conditions. 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:

1. Choroidal hemorrhage.
2. Concomitant severe eye disease
3. Excessive vitreous loss
4. Extremely shallow anterior chamber
5. Microphthalmos
6. Non-age-related cataract
7. Posterior capsular rupture (preventing fixation of IOL)
8. Severe corneal dystrophy
9. Severe optic atrophy
10. Uncontrollable positive pressure
11. Zonular separation (preventing fixation of IOL)
12. Color vision deficiencies
13. Glaucoma
14. Chronic uveitis
15. Diabetic retinopathy
16. Clinically significant macular/RPE changes

WARNINGS

1. As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, endophthalmitis, retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, and transient or persistent glaucoma.
2. The safety and effectiveness of intraocular lens implants have not been substantiated in patients with preexisting ocular conditions (chronic drug miosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplant, previous retinal detachment, and/or iritis, etc.). Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory in meeting the needs of the patient.
3. The long-term effects of intraocular lens implantation have not been determined. Therefore physicians should continue to monitor patients postoperatively on a regular basis.
4. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
5. A secondary iridectomy for pupillary block may be avoided if one or more iridectomies are performed at the time of IOL implantation (Willis, et al., 1985).
6. The safety and effectiveness of a posterior chamber lens, if placed in the anterior chamber, has not been established. Implantation of posterior chamber lenses in the anterior chamber has been shown in some cases to be unsafe (Girard, et al., 1983).
7. Some adverse reactions which have been associated with the implantation of intraocular lenses are: hypopyon, intraocular infection, acute corneal decompensation and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair and retinal detachment repair.
8. Small amounts of lens decentration, occurring with an IOL having a narrow or small optic, may result in a patient experiencing glare or other visual disturbances under certain lighting conditions. Surgeons should consider this potential before implanting an IOL having a narrow or small optic. When implanting a narrow or small optic lens, it is recommended that capsulorhexis be performed.
9. These lenses are not intended, nor should they be used, for clear lens exchange.
10. Postoperative distension of the capsular bag with variable amounts of anterior chamber shallowing and induced myopia have been associated with capsulorhexis techniques and implantation of PMMA, silicone and acrylic posterior chamber lenses (Holtz, 1992).
11. Caution should be used prior to lens encapsulation to avoid lens decentrations or dislocations. Some clinical cases suggest encapsulation occurs within four weeks.
12. There is no clinical data to demonstrate its safety and effectiveness for placement of this lens in the ciliary sulcus.
13. DO NOT re-sterilize the IOL by any method.
14. DO NOT reuse the IOL. This is device for single use only. Reuse of this single-use device may result in serious injury, such as endophthalmitis.
15. DO NOT implant the IOL if the sterility has been compromised or if the sterile package has been unintentionally opened before use.
16. Please dispose of medical waste in the manner required by the local hospital.

It is recommended that OVD be removed from the eye at the close of surgery with emphasis on the space between the posterior capsule and lens. This may be accomplished by gently depressing the IOL optic posteriorly with the I/A tip and using standard irrigation/aspiration techniques to remove the viscoelastic agent from the eye. This should force any trapped viscoelastic anteriorly where it can be easily aspirated.

PRECAUTIONS

1. Store intraocular lenses in dry place at room temperature.
2. Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS®) to rinse and/or soak lenses.
3. Handle lenses carefully to avoid damage to lens surfaces or haptics.
4. Do not attempt to reshape haptics in any way.
5. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.

6. Prior to surgery, prospective patients should be informed of the possible risks and benefits associated with this IOL as well as the risks and benefits associated with cataract surgery. After surgery, physicians should provide information to patients regarding the IOL implanted (https://www.eyedeal.com/products/) along with the implant replay card.
7. Accurate keratometry and biometry in addition to the use of the Toric Calculator (http://calculator.eyedeal.com:39001/) are recommended to achieve optimal visual outcomes.
8. For models PA60ATT, patients with postoperative refractive error may not receive the aspheric optical design benefit without spectacle correction.
9. The maximum exposure of patients in each operation should not exceed 2 intraocular lenses

DIRECTIONS FOR USE

1. Examine the label on the unopened package for model, spherical equivalent power, cylinder power, proper configuration, and expiration date.
2. After opening the cardboard storage container, verify lens case information (e.g., model, power, and serial number) is consistent with information on outer package labeling.
3. Inspect the primary package carefully for tears, cuts, punctures, or other signs that the pouch has been opened or damaged. This device is sterile until the inner primary package is opened. DO NOT implant the IOL if the sterility has been compromised or if the sterile package has been unintentionally opened before use.
4. To remove the lens, open the pouch and transfer the lens case to a sterile environment. Carefully open the lens case to expose the lens. When removing the lens from the lens case, DO NOT grasp the optical area with forceps. Prior to the actual folding process, the lens should be handled by the haptic portion only. Rinse the lens thoroughly using sterile intraocular irrigating solution such as BSS® or BSS PLUS®. DO NOT rinse the lens in solutions other than sterile intraocular irrigating solution.
5. There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.
6. To minimize the occurrence of marks on the lens due to folding, all instrumentation should be scrupulously clean.
7. Recommend using the folding system or equivalent forceps with round edges and smooth surfaces.
8. Examine the IOL carefully prior to insertion to ensure that particles have not adhered during handling.
9. Current techniques, appropriate instrumentation, and a list of their equivalents for folding and implantation are available from Xi'an Eyedeal. Surgeons should verify that appropriate instrumentation is available prior to surgery.

MAGNETIC RESONANCE COMPATIBILITY

The Eyenable® IOLs is magnetic resonance (MR) safe. The IOL consists of acrylate/methacrylate copolymer material, which is a non-conducting, non-metallic, non-magnetic material that poses no known hazards in all magnetic resonance imaging environments.

LIFETIME OF THE IOL

Under normal conditions and medical circumstances, the IOL is expected to be stable indefinitely over the lifetime of the patient.

IMPLANT REPLY CARD

The Implant Reply Card included in the package is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any eye care practitioner that the patient consults in the future. To fill out the patient implant card:
1. Remove implant card sticker from the label set inside carton.
2. Adhere the UDI sticker to the back of Implant Reply Card.
3. Fill out the following information on the card:
• Catalogue number (REF), Lot Number, UDI and Serial Number (SN),
• Date of surgery,
• Patient identification or name
• Health care center or doctor.
Doctors are advised to stick a unique code label on the patient information brochure.
It is a requirement that the patient be given a completed implant reply card along with the patient information brochure.

SERIOUS INCIDENT REPORTING

Any serious incident that may reasonably be regarded as device related should be reported to Xi;an Eyedeal:
By Phone:
+86 029 848 888888
By Email:
info@eyedeal.com
Website:
https://www.eyedeal.com/en/contact/
Each IOL is identified by a serial number which provides traceability, and this information should be given to Xi'an Eyedeal.
NOTE: In Europe, these serious incidents must also be reported to the competent authority for medical devices of the appropriate State.

EXPIRATION DATE

Sterility is guaranteed unless the primary sterilization package is damaged or opened. The expiration date is clearly indicated on the inner label of the lens package. Any lens held after the expiration date should be returned to ***Xi'an Eyedeal*** (See RETURNED GOODS POLICY).

RETURNED GOODS POLICY

Contact your local distributors regarding returned goods policy

CLINICAL BENEFITS of Eyenable® IOL

Improved distance vision with correction of aphakia following cataract extraction and pre-existing corneal astigmatism in adult patients.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

A summary of safety and clinical performance (SSCP) is available in the European database on medical devices (Eudamed) at https://www.ec.europa.eu/tools/eudamed. which can be located using the model number [PA60ATT] after Eudamed go-live

SYMBOLS USED ON LABELING

Symbol	Description of symbol	Symbol	Description of symbol

$Ø_B$	Body diameter (Optic diameter)	$Ø_T$	Overall diameter (Overall length)
D	Diopter	CYL	Cylinder power
STERILE	Sterilized	EC REP	Authorized representative in European Community
	Name and address of the manufacturer		Date of manufacture (YYYY-MM: year-month)
LOT	Lot Number / Batch Code		Use-by date (YYYY-MM: year-month)
	Do not reuse		Do not resterile
SN	Serial number	REF	Catalogue number
	Do not use if package is damaged	STERILE EO	Sterilized using ethylene oxide
	Caution		Consult instructions for use
	Keep dry		Keep away from sunlight
	Patient number		Patient Name or Patient ID
	Date of implantation		Name and address of the healthcare institution /provider
MD	Device name	UDI-DI	UDI-DI Code (HRI)
	Information website for patients		Single sterile barrier system

- **REFERENCES**

1. Boettner, E.A. and Wolter, J.R. Transmission of the ocular media. Invest. Ophthalmol. 1:776-783, 1962.
2. Girard, L.J., et al. Complications of the Simcoe Flexible Loop Phacoprosthesis in the anterior chamber. Ophthalmic Surg. 14(4):332-335, 1983.
3. Holtz, S.J. Postoperative capsular bag distension. J. Cataract Refract. Surg. 16(5):310-317, 1992.
4. Willis, D.A., et al. Pupillary block associated with posterior chamber lenses. Ophthalmic Surg. 16(2):108-109, 1985.

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- EC REP

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