

Instructions for Use

■ **PRODUCT NAME**
Cross-linked Polyisobutylene Aspheric IOL

■ **TRADE NAME**
Eyedeal

■ **DESCRIPTION**

The Cross-linked Polyisobutylene Aspheric IOL (Model PX65AS1) is a foldable single-piece ultra-violet absorbing posterior chamber intraocular lens (henceforth, referred to as IOL). It is an optical implant to replace the human crystalline lens in the visual correction of aphakia in adult patients after cataract removal. The PX65AS1 IOL is made of a high refractive index soft hydrophobic crosslinked polyisobutylene material. It is composed of symmetric biconvex optic design with zero spherical aberration and supporting haptics to ensure proper positions of the IOL optic within the capsule. The physical properties of the lens are shown in the Figure 1.



Figure 1: PHYSICAL CHARACTERISTICS of PX65AS1 IOL
All dimensions in millimeters

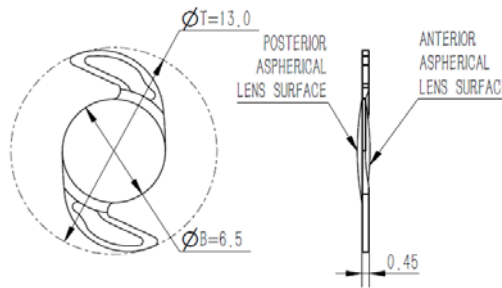
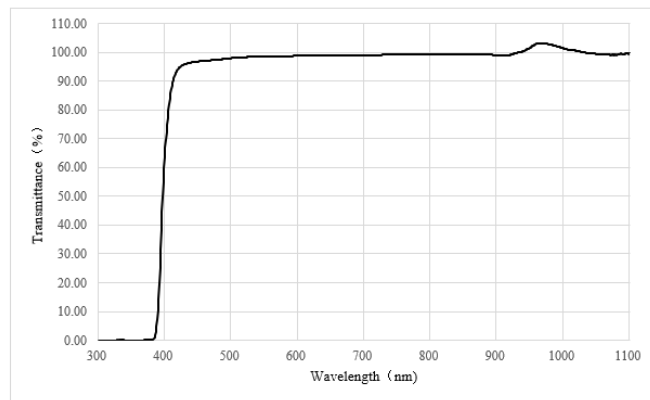


Table 1: Model Characteristics Chart

<i>Items</i>	<i>Description</i>
Model	PX65AS1
Optic Type	Aspheric
Optic Material	Ultraviolet Absorbing Cross-linked polyisobutylene
Spectral Transmission	10% transmittance at 390 nm (UV) for +20.0D
Optical Powers (spherical equivalent diopters)	+0.5 ~ +34.0D +0.5 ~ +30.0 with 0.5D increment +31.0 ~ +34.0 with 1D increment
Index Of Refraction	1.51 at 35°C
Haptic Configuration	Double C type
Haptic Material	Ultraviolet Absorbing Cross-linked polyisobutylene
Haptic Color	Clear
Optic Diameter (mm)	6.5
Overall Length (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 PX65AS1 IOLs made from Cross-linked polyisobutylene with bonded UV-absorber.

■ **INDICATIONS**

The IOL (PX65AS1) is indicated for the replacement of the human lens to achieve visual correction of aphakia 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 PX65AS1 IOLs 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.

■ **MODE OF ACTION**

Posterior chamber intraocular lenses are 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. The effectiveness of these lenses in reducing the incidence of retinal disorders has not been established.

■ **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 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**

Eyedeal recommends using those combinations that have been approved by regulatory authorities and are listed in the table below as compatible with this lens.

model	Diopter range	Injector System (Tip Specification)	incision size	Compatible OVD Types
PX65AS1	+0.5D- +30.0D	ACCUJECT / ACCUJECT DUAL ($\geq 2.2\text{mm}$)	1.8 -3.0mm	based on Sodium hyaluronate, Hydroxypropyl methylcellulose or Sodium hyaluronate + chondroitin sulfate
	+31.0D--+34.0D	ACCUJECT / ACCUJECT DUAL ($\geq 2.4\text{mm}$)	2.0-3.0mm	

■ **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**

When the device is used in strict accordance with the cautions, precautions and warning described in this IFU, there are no known contraindications for the use of the PX65AS1 IOL.

■ **CAUTION**

The listed conditions do not constitute contraindications, but the implantation of an artificial lens may exacerbate the existing situation, which may interfere with diagnosis or treatment of a condition, or may pose an unexpected risk to the patient's eyesight. Patients with preexisting conditions may not achieve the visual acuity 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 (located at <https://www.eyedeal.com/en/products/>) along with the implant card.
7. 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, 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 PX65AS1 IOLs is magnetic resonance (MR) safe. The IOL consists of *polyisobutylene* 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.

■ PATIENT IMPLANT CARD

The Implant 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 label to the back of Implant Card.
 3. Fill out the following information on the card:
 - Date of surgery.
 - Patient identification or name .
 - Health care center or doctor.
 - indication if left or right eye was treated.
 - The Catalogue number (REF), Lot Number, and UDI together with the Serial Number (SN) — these three items may be filled in at the doctor 's discretion according to the actual situation, as this information is already printed on the UDI label.
- It is a requirement that the patient be given a completed implant card .

■ SERIOUS INCIDENT REPORTING

Any serious incident that may reasonably be regarded as device related should be reported to the following companies::

Shanghai International Holding Corp. GmbH (Europe)

By Phone: +49-40-2513175

By Email: shholding@hotmail.com

Xi'an Eyedeal Medical Technology Co., Ltd

By Phone: +86 029 848 888888

By Email: info@eyedeal.com

NOTE: In Europe, 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.

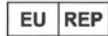























■ CLINICAL BENEFITS of PX65AS1 IOL

Improve distance vision by correcting aphakia following cataract extraction, and enhance the patient's quality of life.

■ 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 [PX65AS1] after Eudamed go-live.

■ SYMBOLS USED ON LABELING

Symbol	Description of symbol	Symbol	Description of symbol
\varnothing_B	Body diameter (Optic diameter)	\varnothing_T	Overall diameter (Overall length)
D	Diopter		Authorized representative in European Community
	Name and address of the manufacturer		Date of manufacture (YYYY-MM: year-month)
	Lot Number / Batch Code		Use-by date (YYYY-MM: year-month)
	Do not reuse		Do not resterile
	Serial number		Catalogue number
	Do not use if package is damaged		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
	Device name		UDI-DI Code (HRI)
	Information website for patients		Sterilized
	Single sterile barrier system	OD	right eye

OS	left eye		
----	----------	--	--

■ **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.



Xi'an Eyedeal Medical Technology Co., Ltd
 Building 3, Technology Enterprise Accelerator, west
 No.2, Qinling Avenue, Hi-tech Zone, 710304 Xi'an China
 Tel: 0086-029-84888888



Shanghai International Holding Corp. GmbH (Europe)
 Eiffestrasse 80, 20537 Hamburg, Germany

■ **ISSUE DATE**

xxxx-xx-xx

■ **REVISION DATE**

xxxx-xx-xx(Rev:xx)