Instructions for Use

CE 2797

- **PRODUCT NAME**
  Hydrophobic Acrylic Aspheric IOL
- **TRADE NAME**
  Eyenable ®
- **DESCRIPTION**

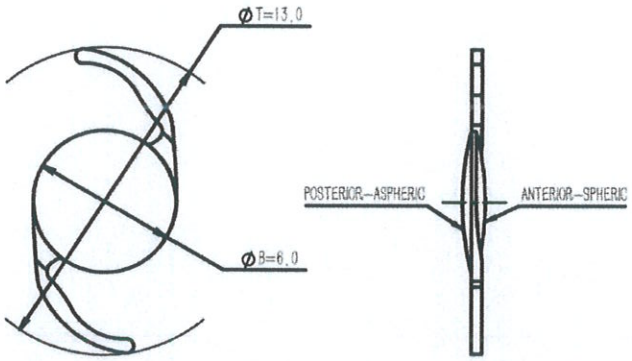
The Eyenable® Hydrophobic Acrylic Aspheric IOL (Model LA60AD1/LA60AM1, henceforth, referred to as Eyenable® IOL/IOL) is a foldable single-piece ultra-violet absorbing posterior chamber preloaded intraocular lens. The Eyenable® IOL consists of a hydrophobic acrylic aspherical intraocular lens (Eyenable ® PA60AS1) and a preloaded system (Accuject dual 2.1-BL /IOLMATIC Injector System 2.2M). It is an optical implant to replace the human crystalline lens in the visual correction of aphakia in adult patients after cataract removal. The Eyenable® PA60AS1 IOL is made of a high refractive index soft hydrophobic acrylic material.

Eyenable® PA60AS1 IOL has an aspheric optic 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. The physical properties of the lens are shown in the Figure 1.

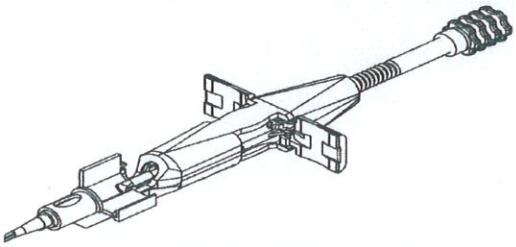
Figure 1: PHYSICAL CHARACTERISTICS of Eyenable® IOL

All dimensions in millimeters

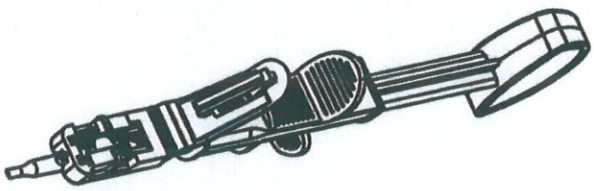
a) Design of the Eyenable ® IOL, Model PA60AS1



b)Preloaded Systems



Accuject dual 2.1-BL- used for LA60AD1

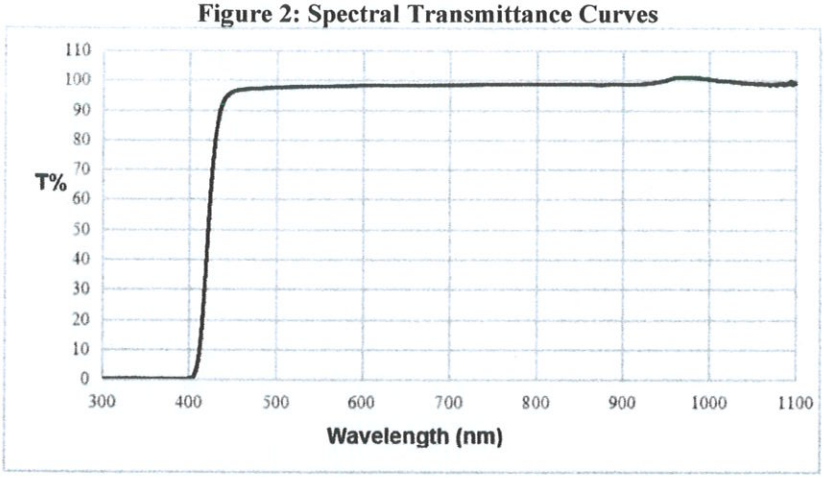


IOLMATIC Injector System 2.2M-used for LA60AM1

Table 1: Model Characteristics Chart

Items	*Description*	
Model	LA60AD1	LA60AM1
Optic Type	Anterior Spherical Surface and Posterior Aspherical 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)	+10.0 ~ +30.0D +10.0 ~ +30.0 with 0.5D 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® PA60AS1 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 (LA60AD1/LA60AM1) 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 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. The aspheric biconvex optic reduces spherical aberration as compared to a standard spherical optic in an average 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 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.
The Eyenable® IOL manufacture recommends the qualified combinations that can be used with this lens are listed in table below.

Model	Diopter range	OphthalmicViscosurgicalDevice (OVD)
LA60AD1&LA60AM1	+10.0D to +30.0D	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 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/products/) along with the implant replay 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 injector 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 package 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. Grasp the corner of the blister box in a sterile environment and fully tear off the top cover portion of Tyvek to remove the preloading injector with IOL. Inspect the preloaded implant system and the IOL and replace the product if: 1) there is damage, particulate matter, or deformation in the tip nozzle area of the introduction head; 2) the preloaded implant system is not intact; 3) the screw rod component of the preloaded implant system has shifted forward; or 4) the IOL has been damaged or is not seated correctly on the loading area.

LA60AD1:

1. Apply the viscoelastic into the distal end of the cartridge tip (Fig. 3) and one drop of viscoelastic on the tip of the silicone tip, and then insert the viscoelastic syringe needle into the viscoelastic injection port of the preloaded implantation system as shown in Fig. 4, and inject the viscoelastic until the viscoelastic fills the loading chamber; requires approximately 0.2 ml of viscoelastic. Scratching of the inner lumen surface of the cartridge tip and the IOL by the viscoelastic syringe needle should be avoided during this process.

Figure 3

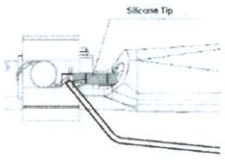


Figure 4

2. Advance the plunger until the blue silicone pad on the plunger hits against the injector body(Fig. 5).This way,leading and trailing haptic are being pushed against the optic body of the lens(Fig. 6).

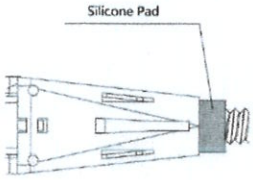


Figure 5

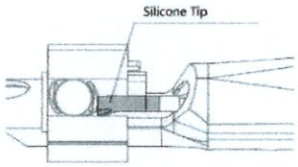


Figure 6

3. Closs the loading chamber until they make a "clicking" sound (Fig. 7) .

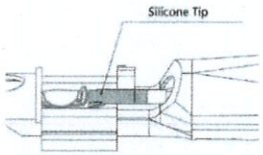
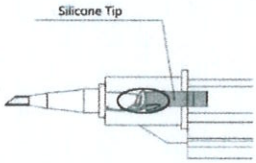


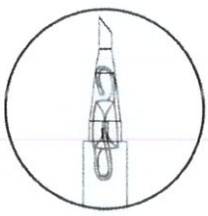
Figure 7

4. Advance the plunger in a gentle, continuous motion (opening the finger handle) or rotate the plunger until half of the elliptical visualisation window turns blue (Figure 8). This process should take at least 6-8 seconds; do not suddenly and rapidly rotate the plunger or advance the plunger, as this may result in improper IOL folding and damage.

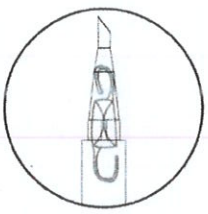
Figure 8



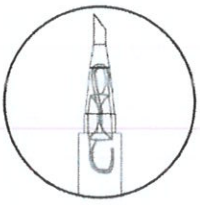
5. Once half of the elliptical visualisation window has turned blue, the IOL is observed to determine the position of the hapic. The blue silicone tip should be in partial contact with the optical edge of the IOL. No part of the IOL should be pushed out of the cartridge tip before passing through the incision. The state of the IOL shown in Figure 10 is an IOL folded state in which implantation can continue to be completed, if an IOL folded state different from that shown in Figure 9 occurs it is recommended that the implantation operation be discontinued and that the procedure be completed using another pre-loaded IOL.



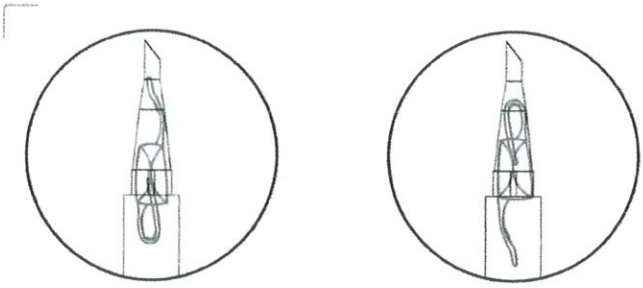
"Forward."



"Forward."



"Forward."



"Forward and according to the placement of the IOL "Forward and fully utilising the actuator extension

The need to rotate the device in conjunction with the " complete IOL insertion."

Figure 9

6. After making sure that the IOL is in the correct position and that the hapics are correctly folded, the implantation of the IOL proceeds, the tip of the cartridge tip nozzle is inserted through the incision and the tip of the nozzle is placed at the anterior capsule opening.
7. Push the plunger in a gentle, continuous motion or rotate the plunger to move the silicone head gently forward. Do not rotate the plunger or push the plunger forward rapidly as damage to the IOL may occur. It is recommended that a minimum of 5 seconds be required from the time the IOL is pushed out of the oval viewing window to the time it is disengaged from the cartridge tip nozzle. As the IOL is pushed out of the cartridge tip of the nozzle, hapic into the capsular bag and continue to slowly push forward or rotate the plunger to allow the silicone tip to continue to push the IOL forward. As the IOL optical zone is pushed out of the cartridge nozzle tip, the implant system is rotated as needed to ensure that the IOL unfolds upward on the anterior surface within the capsular bag and lies in a plane parallel to the iris.

Note: If during the implantation process, there is a stuttering of the operation, too much resistance to pushing, and the pushing process is not smooth enough, it is recommended to stop the implantation operation and use another pre-loaded IOL.

8. The IOL is adjusted for position within the capsular bag using the appropriate instrumentation.
9. Safely discard pre-loaded implant systems as medical waste upon request.

LA60AM1:

1. Ensure that the lens holder and IOL are correctly mounted. Dispense viscoelastic beneath the IOL through the viscoelastic port (The viscoelastic drop should reach the IOL from the bottom,shown in Figure 10),additionally add some viscoelastic on top of the IOL,this step requires approximately 0.2 ml of viscoelastic. Scratches to the cartridge tip and the IOL should be avoided during this procedure .

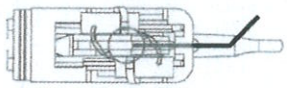


Figure 10

2. Activate both sliders and ensure the haptic are correctly folded over the optic.Also chech,that the haptics are not trapped in the slider slots (Figure 11). If they are not stuck in the sliders, use another preloaded IOL.

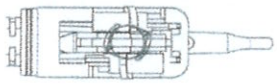


Figure 11

3. Close the cartridge lid gently in one continuous motion until it clicks (Fig. 12).Check that the IOL is down folded correctly by finding the haptic tips(Fig. 13). If the IOL is not folded correctly, use another pre-loaded IOL.

Figure 12

Figure 13

4. Inject the IOL with a continuous and slow push (around 5-8 seconds for the complete injection). As the IOL is pushed out of the tip of the nozzle, place the guide haptics into the capsular bag and continue to slowly push forward the plunger to allow the silicone tip to continue to push the IOL forward. As the IOL optical zone is pushed out of the cartridge nozzle tip, the implant system is rotated as needed to ensure that the IOL unfolds upward on the anterior surface within the capsular bag and lies in a plane parallel to the iris.

Note: If during the implantation process, there is a stuttering of the operation, too much resistance to pushing, and the pushing process is not smooth enough, it is recommended to stop the implantation operation and use another pre-loaded IOL.

5. The IOL is adjusted for position within the capsular bag using the appropriate instrumentation.
6. Safely discard pre-loaded implant systems as medical waste upon request.

- **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), Medical device (MD),
• 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.

- **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 [LA60AD1/LA60AM1] 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	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

31	Date of implantation		Name and address of the healthcare institution /provider
MD	Device name	UDI-DI	UDI-DI Code (HRI)
	Information website for patients	STERILE	Sterilized
	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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Tel: 0086-029-84888888

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

- **ISSUE DATE**
April 7, 2024
- **REVISION DATE**
N/A