CE
2460
An ISO 13485 certified company

MONOFOCAL HYDROPHOBIC ACRYLIC FOLDABLE IOL

INSTRUCTION FOR USE

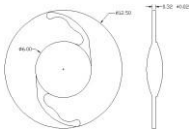
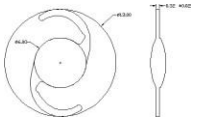
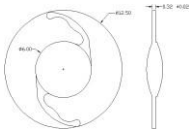
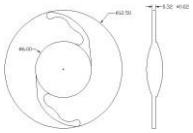
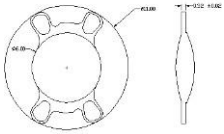
1. INTENDED USE OF THE IOL:

Monofocal Hydrophobic Acrylic Foldable IOL are intended to be positioned in the posterior chamber of the eye, after replacing the human natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia

2. DEVICE DETAILS:

Implantable Life Time: -15 years

All our lenses are compatible with all our lens delivery system models. They can come in preloaded or non-preloaded form depending upon Surgeon's requirement.

Model Numbers	Color/Material	Haptic Style	Optic	Optic Dia./Overall dia.(mm)	Haptic Angulation	Design
HLL260125CRA HLL260125CRCA, HLL260125CRA^{PL} HLL260125CRCA^{PL} HLL260125CRBA, HLL260125CRBA^{PL}	Clear /Hydrophobic Acrylic	L loop	Aspheric, Monofocal	6.00/12.50	0°	
HCL160130CRA, HCL160130CRCA HCL160130CRBA HCL160130CRA^{PL} HCL160130CRCA^{PL} HCL160130CRBA^{PL}	Clear Hydrophobic Acrylic	C loop	Aspheric, Monofocal	6.00/13.00	0°	
HLL360130EYCA HLL360130NYA HLL360130NYA^{PL} HLL360130EYCA^{PL}	Yellow Hydrophobic Acrylic	L loop	Aspheric, Monofocal	6.00/13.00	0°	
HLL260125NYA HLL260125NYA^{PL} HLL260125EYA HLL260125EYA^{PL}	Yellow Hydrophobic Acrylic	L loop	Aspheric, Monofocal	6.00/12.50	0°	
HQL160110CRA, HQL160110CRA^{PL}	Clear Hydrophobic Acrylic	Quadra	Aspheric, Monofocal	6.00/11.00	0°	

3. DEVICE DESCRIPTION:

Intraocular lenses (IOLs) are the medical devices that have been around since the late 1940s and were the first devices to be implanted in the body. An intraocular lens implant is an artificial replacement of natural lens to treat cataract. The cataract surgery started with the first IOL implantation by Sir Harold Ridley in 1949.However, the real beginning of usable IOL technology occurred after 1970s. The materials that have been used to manufacture intraocular lens includes poly methyl methacrylate (PMMA), silicone, acrylic materials such as hydrophobic acrylic

and hydrophilic acrylic. The hydrophobic material is one of the commonly used material groups because of its folding and unfolding abilities in a controlled fashion at room temperature. The materials have very low water content, a high refractive index, and usually, a high memory, which makes it a suitable choice.In addition to a wide range of material types, IOLs are also available in many optic designs such as monofocal, bi-focal, tri-focal, and accommodative.

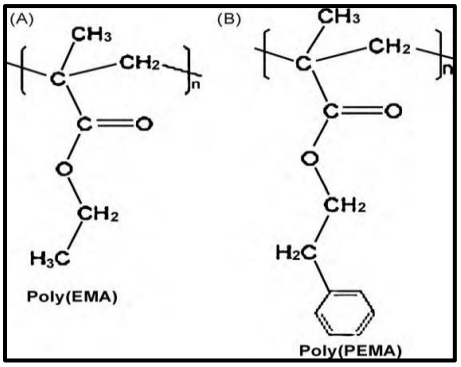
Intraocular lens is composed of two elements: 1) Optic, and 2) Haptic. The optic is the small centre portion that acts as an artificial lens, and the haptic is the side structure that holds the lens in place in a capsular bag.

A Monofocal Hydrophobic Acrylic Foldable IOL is an intraocular lens with a fixed focus for one distance. The natural lens is protected against phototoxic UV light due to the filter properties of cornea, aqueous humor, lens and retina. After cataract surgery, it becomes important to protect the eye from UV radiation through artificial lens. The hydrophobic Monofocal lens has a UV filter that allows transmission of <10% of light of wavelength 360 nm or lower which ensures protection of the eye from UV radiation. The Monofocal Hydrophobic Acrylic Foldable IOLs are available in yellow optic tint, which is known to provide better contrast sensitivity by absorbing blue light and possibly protect the retina from damage and development of age-related macular degeneration (AMD).

4. DEVICE MATERIAL DESCRIPTION:

Monofocal Hydrophobic Acrylic Foldable IOL is made from a series of co-polymers of acrylate and methacrylate derived from rigid polymethyl methacrylate (PMMA), to make them foldable and durable.

The foldable hydrophobic acrylic IOLs, referred to as acrylic IOLs, are esters of poly(meth)acrylic acid, mainly poly(2-phenethyl (meth)acrylate) – Poly (PEMA), poly(ethyl(meth)acrylate) – Poly (EMA), and poly(2,2,2-trifluoroethyl methacrylate) – Poly (TFEMA).



Chemical structures – Poly (EMA) and Poly (PEMA)

5. DEVICE TECHNICAL SPECIFICATIONS:

- Diopter Range: -10.0D to +45.0D (applicable to the Asian market only)
- Lens Delivery System: ErgoTouch (ODC) / Comport (RET), Available in Preloaded System
- MTF value: ≥ 0.43
- Optic Resolution: ≥ 70%
- Optic Material : UV Absorbing Hydrophobic acrylic foldable material
- Optic Diameter: 5.0mm – 7.0mm (0.25 Increments)
- Haptic Angle: 0° to 5°
- Overall diameter / length: 11 mm - 13.50 mm (0.50 Increments)
- Haptic Configuration: C loop, L loop, Quadra loop
- Configuration: Bi-convex
- Optic design: Aspheric, Square edge, Monofocal

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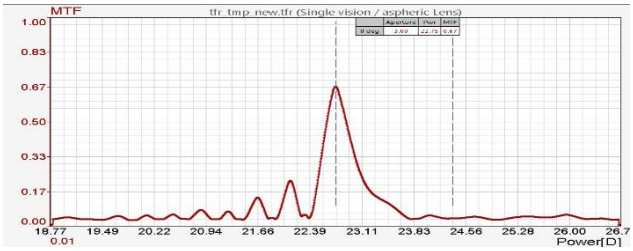
- Ref. Index: 1.48-1.56
- Colour: Clear, Yellow
- Inner Packing: Single IOL in Lens case, Single IOL in Preloaded system
- Outer packing: Single Pack, Preloaded Pack

Modulation Transfer Function (Fig. 1)



6. MEDICAL INDICATION:

Monofocal Hydrophobic Acrylic Foldable Intra Ocular Lens are indicated for the replacement of the human natural lens to achieve visual correction of aphakia in patients with forty years of age and above when extra capsular cataract extraction or phacoemulsification is performed. These IOLs are intended for placement in the capsular bag.

7. MODE OF ACTION:

When implanted in the posterior chamber of the eye, the IOL is intended to replace the natural crystalline lens and function as a refracting medium in the correction of aphakia.

8. INTENDED USER:

Ophthalmic surgeons only.

9. TARGET POPULATION:

Aphakic adult patients of age 18 years and above.

10. CALCULATION OF IOL POWER:

It is recommended that the surgeon use a power calculation method in which he is most familiar and comfortable with in general, the power of the IOL for each patient can be estimated from prior refractive error or calculated from the corneal radius, depth of the anterior chamber and axial length of the eye according to formulas in corresponding literature.

11. A CONSTANT INFORMATION:

The constant listed on the outer label is presented as a guideline and is a starting point for implant power calculation. It is recommended that surgeon calculates their own personalized A constant based on clinical experience with the particular IOL models, surgical techniques, measuring equipments and postoperative results.

12. METHOD OF STERILIZATION:

Intraocular lens is ETO sterilized in a lens case or preloaded system contained within a sealed sterilizable pouch. The contents of the pouch are sterile unless the package is damaged or opened.

13. CLINICAL BENEFIT OFMONOFOCAL HYDROPHOBIC ACRYLIC FOLDABLE IOL:

- Provides enhanced, clear optics for lens-based surgery
- Prevent hydration from entering into the lens after implantation
- Intraocular stability

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- Lower incidence of PCO
- Improvement in Visual acuity
- Improvement in Near vision and spectacle independence
- Improvement in Contrast Sensitivity of Patients
- Improvement in Near vision and spectacle independence
- Monofocal IOLs increase depth of focus in patients
- Monofocal IOLs provide better satisfaction for patient

14. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE REFERRED:

Link for the availability to SSCP: Link to be provided after notified body acceptance of SSCP.

15. CONDITIONS OF STORAGE & TRANSPORT:

Hydrophobic intraocular lenses are to be Store & transport between 5^{o}C to 40^{o} C& Keep away from sun light.

16. RECOMMENDATION FOR CHOOSING LENS DELIVERY SYSTEM:

The use of a lens delivery system is essential for the implantation of intraocular lens. It consists of cartridge, injector and cushion. Lens Delivery System also can supply in Single pack depending upon Surgeon's requirement.
All Monofocal Hydrophobic IOL is supplied in single/Regular pack, if IOL packed in lens case pack.
All monofocal Hydrophobic IOL is supplied in preloaded pack also, if IOL packed in preloaded system and sterilized by ETO.

Cartridge

Injector

17. INSTRUCTION FOR THE REMOVAL OF IOL FROM CONTAINER:

- Examine the label on the unopened package for model, power, configuration, and expiration date.
- After opening the cardboard storage container verify the information provided on Pouch/ Lens case/ blister pouch of preloaded system (e.g. model, power and serial number) is consistent with information on outer package labelling.
- Remove the lens case from peelable pouch.
- Open the lens case & take out the IOL.
- In case of IOL packed in preloaded system, a leaflet containing diagrammatic representation for handling of preloaded system has been provided separately.

- Exercise caution when removing the IOL as the IOL can be easily damaged. Inspect IOL for debris and damage. The IOL should be handled by the haptic portion only.

18. INSTRUCTION FOR USE:

Preparatory Steps

- Prior to the implant, examine the IOL package for IOL size, Spherical Power, Cylinder Power, Axis of the IOL, expiration date and other specifications.
- Check the integrity of the sterile packaging before use.
- Do not use if packaging integrity is found compromised.
- The IOL must be opened in a sterile environment and used as soon as possible after opening the box.
- After opening, verify primary package information (e.g., model, power, serial number) is consistent with the information on the outer package labeling.
- Open the pouch then open the lens case & take out the lens in a sterile environment.
- Pick the lens haptic gently with the help of forceps while ensuring that no optic part is in contact with the forceps.
- Examine the lens optics as well as haptics part to ensure that no dust or particles have attached to it, and examine the lens optical surface for other defects.
- Soak & Rinse the IOL with a sterile balanced salt solution until ready for implantation.
- To remove the IOL, open the pouch and transfer the case to a sterile environment. Carefully open the case to expose the IOL. When removing the IOL from the case, DO NOT grasp the optical area with forceps. Prior to the actual folding process, the IOL should be handled by the haptic portion only.
- Rinse the IOL thoroughly using sterile intraocular irrigating solution (BSS, WFI etc.).
- There are various surgical procedures, which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.
- To minimize the occurrence of marks on the IOL due to folding, all instrumentation should be scrupulously clean.
- It is recommended to use a forceps with round edges and smooth surface. Surgeons should verify that appropriate instrumentation is available prior to surgery.
- Note: Prior to insertion the IOL should be carefully examined to ensure that particles have not adhered during handling.

Before Surgery	After Surgery
If you take medicine for your heart, blood pressure, or asthma, you may take your medicine with a sip of water in the morning of your surgery. If you have diabetes, please check with your doctor about whether to take your medicine before surgery.	Your eye may feel like it has grit or sand in it after the operation. Your eye may itch and be more sensitive to light. These feelings are normal and should gradually get better in the days after surgery. Do not rub, scratch, or press on your eye.
Do not eat or drink anything after midnight the night before surgery.	Redness is normal for the first few days. This should get better in three to four days after surgery.
Bring your medicine that you are taking with you in the morning of surgery.	If you are suggested to wear an eye shield, use it as directed by your doctor. Do not remove it until they say.
Your doctor may prescribe some eye drops for several days before the surgery. Follow the instructions on how to use them.	You may want to wear glasses during the daytime hours to prevent anything from touching your eye and to remind you not to touch it.
Lab tests may be done before your surgery. Your	You may want to wear sunglasses when outside. The

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doctor will suggest the tests needed.	operative eye may be more sensitive to sunlight which can cause pain.
Wash your hair and face the morning of the surgery.	Your doctor may ask you to use eye drops to help healing and decrease the risk of infection. Ask your doctor about how to use your eye drops and use it as in the prescription.
You can brush your teeth that morning, but do not swallow any water.	Avoid smoke, dust, and aerosol spray. And try not to bend from the waist to pick up objects on the floor. Do not lift any heavy objects. You can walk, climb stairs, and do light household chores.
Do not wear makeup, jewelry, nail polish, lotions, or perfumes and wear comfortable clothes.	It will not harm your eyes to read or watch TV.
You must have a responsible adult to drive you home after your surgery.	Always wash your hands before using eye drops or having your hands near your eyes for any reason.
	You may return to normal activities when your doctor allows. Ask your doctor when you can resume driving.

OPERATIVE PROTOCOL

The protocol of implantation is the responsibility of the surgeon. He must decide the procedure which is the most adequate based on the techniques which are most current and best executed on his own experience.

DISPOSAL

Discarded IOLs and Preloaded Systems (used or unused(if opened from sterile packaging)) are classified as medical (clinical) waste that can be a potential source of infection or microbial hazard and must be disposed of according to the regulatory practices.

Preloaded IOL instructions for use:

The IOL is supplied sterile and preloaded in the delivery system within a sterilized pack. The pack is sterilized and should only be opened under sterile conditions. An implant card is included in the pack to record all implant information (the supplied labels may be used). It shall be given to the patient, with the instruction to keep this card. The card should be shown to any eye care professional the patient visits in future.

The preloaded injector should only be used for the placement of IOLs into the eye.

1. Completely peel back the lid of the outer tray.
2. Prior to implanting, examine the lens label on the unopened inner package for model, type, power, proper configuration and expiration date.
3. The lens may be soaked in sterile balanced salt solution until ready for implantation.
4. Carefully peel back the lid half way down the inner tray.
5. Carefully drain the saline from the inner tray and peel off remaining lid. Do not remove the injector from the blister tray. Do not wait more than 3 minutes before adding OVD - Dehydration risk.
6. Non-toothed, polished instruments must be used when handling the IOL.
7. OSI recommends that saline is not used as the sole lubricating agent, but in combination with a viscoelastic solution. The use of a sodium hyaluronate-based viscoelastic is recommended. Insert the viscoelastic cannula into the opening marked with an arrow on the cartridge and apply sufficient OVD to completely fill the cartridge.
8. Keep the injector in the tray and close the cartridge firmly together by pushing the moving half of the cartridge against the fixed half until you hear it click closed.
9. Check both clips have “clicked” shut and secured the cartridge.
10. Gently lift out the injector from the tray.

11. Press the plunger in a slow and controlled manner. If excessive resistance is felt this could indicate a blockage; stop and discard the injector and lens. In the case of IOL rotation during ejection from the nozzle, gently rotate the injector in the opposite direction to counteract any movement. Stop depressing the plunger when the IOL exits the nozzle. Discard the injector after use.
12. Irrigate/aspirate to eliminate any OVD residues from the bag, especially between the IOL and posterior capsule.
13. The anterior continuous curvilinear capsulorrhexis should be 360^{o} and just cover the anterior edge of the IOL optic by 0.5 to 1.0 mm.

19. CONTENTS OF BOX:

The packaging contains sterile product, instruction for use, patient implant card, patient card label, Informative instructions leaflet, Patient Information Leaflet and peelable labels. The peelable labels display the Device name, Serial number, Lot No., IOL diopter, model number, UDI. These labels are designed to be affixed to the patients hospital chart and the physicians chart. One of these labels should be affixed to the patient's identification card contained in the IOL box and given to the patient as a permanent record of their implant.

20. CONTRAINDICATIONS:

Surgeons should explore the use of alternative method of aphakia correction and consider IOL implantation, only if alternatives are deemed unsatisfactory to meet the needs of the patient.Implantation is not advisable with the diagnosis or the treatment of pathology, or present a risk to the sight of the patient. These conditions are (non-exhaustive list):

- Choroidal haemorrhage
- Chronic severe uveitis
- Excessive vitreous loss
- Extremely shallow anterior chamber
- Medically uncontrolled glaucoma & Excessive vitreous pressure
- Microphthalmos
- Aniridia
- Posterior capsular rupture & Zonular separation (preventing fixation of IOL)
- Proliferative diabetic retinopathy (severe)
- Severe corneal dystrophy & optic atrophy
- Rubeosis iridis-Congenital bilateral cataract, recurrent anterior or posterior segment inflammation of unknown etiology, Rubella cataract
- Retinal detachment
- Iris atrophy
- Severe ametropia and aniseikonia
- IOL replacement or extraction
- Excessive intraoperative vitreous loss
- Haemorrhage

In above condition, IOL implantation can be done with judgement of Surgeon.

21. COMPLICATIONS AND ADVERSE EVENTS:

As with any surgical procedure, there is risk involved. The possible adverse effects and complications accompanying a cataract surgery may be the following (non-exhaustive list):

- Posterior capsule opacification
- Cystoid Macular edema
- Corneal edema
- Pupillary block
- Iridocyclitis
- Hyalites
- Endophthalmia and Panophthalmia
- Iritis
- Recurrent anterior or posterior segment inflammation of unknown etiology
- IOL precipitates
- IOL Decentration
- IOL dislocation and subluxation
- TASS (Toxic anterior segment syndrome)
- There may be short-term interferences with diagnostic tools such as optical torch or MRI; risks related to this have been captured in risk management and residual risks are acceptable because of the low probability of occurrence of harm. The user is informed about such risks via IFU.
- Adverse reactions (hypopyon, Intraocular infection, acute corneal decompensation and/or secondary surgical intervention) and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were previously expected in nature, severity or degree of incidence shall be reported to the manufacturer (OSI)and the competent authority of the Member State in which the user and/or patient is established.

22. ADVERSE EVENTS REPORTED FROM CLINICAL STUDY:

- Macular edema or retinal detachment

23. RESIDUAL RISKS

The finished device is having the Residual Risks such as

- IOL Dislocation
- Allergic Reaction
- Undesired vision correction

24. WARNINGS & PRECAUTIONS:

- Do not re-sterilize these Intraocular Lenses by any methods. If re-sterilized, can cause infection.
- Use only sterile intraocular irrigating solution (BSS, WFI etc.)to rinse and/or soak IOLs to retain sterile condition and avoid contamination.

- Do not re-use the IOL. If a IOL is reused, it can cause loss of vision/serious complication.
- The IOL must be implanted in the capsular bag.
- Do not use the intraocular lens after the expiration date shown on the outside package label. After expiry, sterility is not retained and can cause infection.
- Handle the intraocular lens carefully. Rough handling or excessive handling may damage the IOL.
- A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and /or assisted in numerous surgical implantations and successfully completed one or more courses on intraocular lenses prior to attempting to implant IOLs. Read this instruction for use carefully before implanting an IOL.
- The surgeon must be aware of the risk of opacification of the intraocular lens, which may necessitate IOL removal.
- All cases of IOL removal must be reported to OSI
- In case of any adverse event noted, contact manufacturer (OSI) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs. A report describing the adverse event, therapy adopted, traceability detail of the lens used will be requested.
- In order to successfully implant intraocular lens, choose right lens delivery system.
- OSI will not be responsible for any of the damage occurred to patient due to not following above listed warnings. The risks associated are: deterioration of IOL, contamination, infection or loss of vision in operated eye.

IOL is void of all warranties expressed or implied if

- IOL is re sterilized by any one.
- IOL is repackaged by anyone.
- IOL is altered in any manner.

PATIENT INFORMATION

The expected device lifetime is 15 years. The surgeon performing the implantation must inform the patient about the implant and all known side effects and risks. The patient should be instructed to properly inform the doctor in charge about any side-effects after implantation. In case of any serious incident the manufacturer has to be immediately informed

25. EXPIRATION DATE INFORMATION:

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should not be used.

26. RETURN GOODS POLICY:

Ophthalmic Solution Inc. accepts returned IOLs for exchanges only in case of manufacturing defect. No cash refunds will be issued. To return IOLs, you must first obtain a Return authorization number from customer services department. No returned goods will be accepted without proper authorization number. Returned IOLs should be shipped by traceable method. No credit will be given to lost or damaged IOLs in shipment. IOLs will be replaced as long as they are returned within six months of their original invoice date.

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27. DISPOSE OF USED MEDICAL DEVICE CONTAINER/PACKAGE:

- Do not dispose damaged or explanted device or its packing with household trash. Disposal of devices and its packaging is considered a biohazard. Follow local regulatory guidelines for disposing off devices and its packaging safely.
- Put used device package in disposal container as per your community guidelines for the right way to dispose of your disposal container.
- You may use a household container that is: made of a heavy-duty plastic, can be closed with a tight-fitting, puncture-proof lid, without sharps being able to come out, uprightand stable during use, leak resistant, properly labeled to warn of hazardous waste insidethe container.
- When your disposal container is almost full, you will need to follow your communityguidelines for the right way to dispose of your disposal container. There may be state orlocal laws about how you should throw away used device package.
- Do not recycle your used sharps disposal container.

Symbol	information	Symbol	information
EC REP	CEpartner4U BV ESDOORNLAAN 13 3951 DB MAARN THE NETHERLANDS www.CEpartner4U.com		Ophthalmic Solution Inc. 820, Corridor Park Blvd., Knoxville, TN 37932, USA www.osilens.com Email: info@osilens.com
	Do Not Use If Package Is Damaged or unintentionally opened before use		Do Not re-use
	Do not resterilize		Keep away from sunlight
	Consult Instructions for Use		Keep dry
MD	Medical Device		Single sterile barrier system with protective packaging inside

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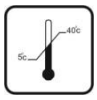
MONOFOCAL HYDROPHOBIC ACRYLIC FOLDABLE IOL

EC REP	Authorized Representative in the european community	STERILE	Sterilized using steam
	Storage Condition between 5°C to 40°C		Manufacturer
	Date of manufacture		Expiry Date
LOT	Sterile Batch No.	UDI	Unique device identifier
SN	Serial number	#	Model number
CE 2460	DNV – Notified Body Number		