CE 2460

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MONOFOCAL HYDROPHILIC ACRYLIC FOLDABLE IOL

INSTRUCTION FOR USE

1. INTENDED USE OF THE IOL:

Hydrophilic monofocal intraocular lenses are indicated for the replacement of human crystalline lens to achieve visual correction of aphakia in patients when extracapsular cataract extraction or phacoemulsification is performed. These lenses are intended for placement in the capsular bag.

2. DEVICE DETAILS:

Life Time of the device:- 15 years

All our lenses are compatible for all our lens delivery system". of all sizes. They can come in preloaded or non-preloaded form (Single) depending upon Surgeon's requirement.

*Refer Annex A for Product specification.

3. DEVICE DESCRIPTION:

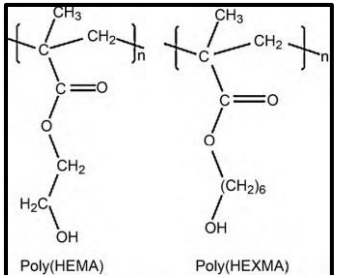
Intraocular Lens mainly consists of two parts: 1) Optic, and 2) Haptic. Optic is the small center portion that acts as an artificial lens, and haptic is the side structure that holds the lens in place once implanted. This technical documentation comprises a group of hydrophilic monofocal IOLs with a water content of 25% and 26%. These IOLs are available in clear, yellow colours.

4. DEVICE MATERIAL DESCRIPTION:

Hydrophilic IOL devices consist of a network of hydrophilic chains that are able to absorb water, thus also called as hydrogels. Because of their water-absorbing capacity, they are well-suited for long-term application in an aqueous environment.

The polyacrylic network is prepared by free-radical co-polymerization of a hydrophilic monomer, 2-hydroxyethyl methacrylate (HEMA) and 6-hydroxyhexyl methacrylate (HEXMA) with a cross-linking agent (ethylene glycol dimethacrylate (EGDMA), for instance).

In the dry state, these materials are rigid and unfoldable, upon immersion in water, they become flexible and soft resulting in a hydrogel. Normally, the equilibrium water content of the hydrophilic acrylic IOLs is in the range of 18–38 wt%. Our hydrophilic monofocal IOLs contain 25 and 26% water contents and are available in clear, yellow colors.

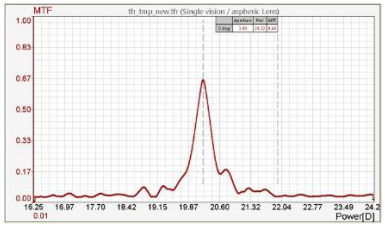


Chemical structures – Poly (HEMA) and Poly (HEXMA)

5. DEVICE TECHNICAL SPECIFICATIONS:

- Diopter Range: -20.0D to +60.0D (applicable to the Asian market only)
- Lens Delivery System: ErgoTouch (ODC) / Comport (RET)
- MTF value: ≥ 0.43
- Optic Resolution: ≥ 70%
- Optic diameter: 5.0mm – 7.0mm(0.25 Increments)
- Overall diameter /length: 11mm – 13.50 mm(0.50 Increments)
- Haptic Angle: 0 º– 10º
- Optic material: Hydrophilic Acrylic with 25% & 26% water content
- Optic design: Aspheric, Square edge, Monofocal
- Configuration: Bi-convex
- Color: Clear, Yellow
- Haptic configuration: L-loop , C-Loop, Flex loop , Quadra,
- Ref. Index: 1.45-1.50
- Available in Preloaded System

Modulation Transfer Function (Fig. 1)



6. MEDICAL INDICATION:

Hydrophilic monofocal intraocular lenses are indicated for the replacement of human crystalline lens to achieve visual correction of aphakia in patients when extracapsular cataract extraction or phacoemulsification is performed. These lenses 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 develop your own constant appropriate for you based on clinical experience with the particular IOL models,

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surgical techniques, measuring equipment and postoperative results.

12. METHOD OF STERILIZATION:

Intraocular lens is steam sterilized in a lens vial or blister or preloaded container contained within a sealed sterilizable pouch. The contents of the pouch/vial are sterile unless the package is damaged or opened.

13. CLINICAL BENEFIT OFMONOFOCAL HYDROPHILIC ACRYLIC FOLDABLE IOL:

Compared to regular intraocular lenses (IOL), monofocal IOLs can help you see near distances and reduce the need for glasses or "readers." It can also help patients who have astigmatism.

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:

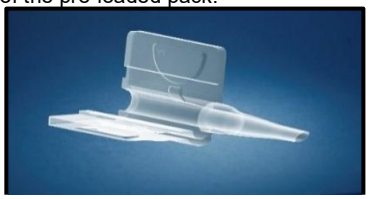
Hydrophilic intraocular lenses are to be Store & transport between 5ºC to 40º C& Keep away from sun light.

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.

Out of three packing configurations of IOL (regular/Single, combo and pre-loaded), lens delivery system is supplied with IOL in case of combo and pre-loaded pack.

Lens delivery system is supplied separately in the same box as that of IOL in case of combo pack whereas the lens is pre-loaded in lens delivery system in case of the pre-loaded pack.



Catridge

Injector

*Kindly note that the preloaded combinations are available in above identified compatibilities as per the surgeons requirements.

Refer Annex B for model compatibility.

17. INSTRUCTION FOR THE REMOVAL OF IOL FROM CONTAINER:

- Remove IOL vial from peelable pouch. Firmly hold vial in one hand and unscrew the cap with your fingers. Remove the rubber stopper and remove the IOL from the vial.
- In case vial is having Holder device then take out the Holder on which IOL is mounted, open the Holder carefully and take out the IOL.
- In case vial is having Holder Folder device then take out the Holder Folder on which IOL is mounted and fold the IOL with the device.
- If IOL packed in Blister, remove IOL blister from peelable pouch, firmly hold blister in one hand and pull the aluminum lid carefully and take out the IOL.
- In case Blister is having Holder device then take out the Holder on which IOL is mounted, open the Holder carefully and 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:

In order to avoid temporary opaqueness at the time of implantation of the only current method recommended is to equilibrate the IOL at 25° C prior to implantation for a minimum of 60 minutes.

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 blister or screw cap or rubber stopper & 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.
- Grasp the IOL by the haptic and rinse in a balanced saline solution prior to implantation into the eye. Use the IOL immediately. Do not leave the IOL exposed to air for too long as it will dehydrate.
- It is imperative that the IOL be placed in the capsular bag and highly recommended that an extra capsular cataract extraction procedure be used.

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.

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Before Surgery	After Surgery
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 doctor will suggest the tests needed.	You may want to wear sunglasses when outside. The 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 Lens Delivery 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 360º 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 hemorrhage
- Chronic severe uveitis

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- 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
- Rubeosisiridis-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
- Hemorrhage

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.
- As in any surgery , risks are present, much more with this type of iol that is implanted in case patients have already had complications of rupture or capsular removal. Other complications are: dislocations or iol tilting, tearing of self blocking plug and/or haptics' parts of iol both during loading of iol in the cartridge and during pulling out plug from eyeball on the bed of scleral flap, hyphema and / or emovitreo, acute or chronic inflammation, endothelial injury, endophthalmitis, extrusion of self blocking plugs from the sclera and conjunctiva, chronic trauma of the root and/or rear portion of the iris, pigment dispersion, secondary glaucoma, transitional overtone, retinal detachment, vitritis, cystoid edema, pupillary membrane, iris prolapse, iponion. 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 should be promptly reported to OSI.

22. ADVERSE EVENTS REPORTED FROM CLINICAL STUDY:

- raised IOP,
- redness of the eye,
- eye pain,
- corneal stromaoedema
- cystoid macular oedema

23. RESIDUAL RISKS

The finished device is having the Residual Risks such as

- IOL Dislocation,
- Allergic Reaction,
- Undesired vision correction,
- Inconvenience to patient,
- Environmental Contamination.

24. WARNINGS & PRECAUTIONS:

- Do not re-sterilize Intraocular Lens by any methods. If re-sterilized, the lens may lose its functionality and may lead to infection.
- Use only sterile intraocular irrigating solution to rinse and/or soak IOLs to retain sterile condition and avoid contamination.
- Once packaging has been opened, the intraocular lens must be used immediately. The IOLs of Hydrophilic nature can cause the IOL to absorb substances with which it comes into contact, such as, disinfectants, medicines, blood cells, etc. This may cause a "Toxic IOL Syndrome". Rinse the IOL carefully before implantations with sterile balance salt solution or balanced saline solution.
- Do not re-use the IOL If IOL is reused, it can cause loss of vision/serious complication.
- 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. Handle the lens by haptic.
- 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.
- 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 Ophthalmic Solution Inc.
- In case of any adverse event noted, contact manufacturer (Ophthalmic Solution Inc.) 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.

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- When the preloaded system is used improperly, the haptics of the IOL, may become broken, please refer to the specific "Instruction for use of Preloaded system", provided with the IOL Pack.
- Check the surface of the lens by looking through the vial. In case of opacity of the surface, do not use the lens and recondition it as above specified. In case the opacity is noted when the vial has already been opened, do not use the lens.

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.

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, upright and stable during use, leak resistant, properly labeled to warn of hazardous waste inside the container.
- When your disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your disposal container. There may be state or local laws about how you should throw away used device package.
- Do not recycle your used sharps disposal container.

EC REP CEpartner4U Esdoornlaan, 13 3951DB Maarn Netherlands office@cepartner4u.com +31343442524	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
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

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LOT Sterile Batch No.	UDI Unique device identifier

SN Serial number	# Model number
CE 2460	DNV – Notified Body Number

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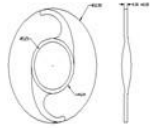
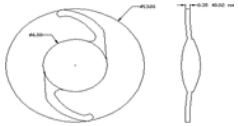
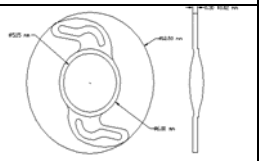
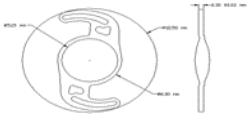
Annex A: Model information

Model Number	Technical parameter								
	Loop	Optic Size	Overall Size	Material	Diopter Range	Optic Design	Haptic Angulation	Color	Picture
CL160125CR6A/AS62	C loop	6	12.5	Hydrophilic 26%	(-) 20 to (+) 60 D	Monofocal	0°	Clear	
CL160130CR6A	C loop	6	13	Hydrophilic 26%	(-) 20 to (+) 60 D	Monofocal	5°	Clear	
FL160125CR6A	Flex loop	6	12.5	Hydrophilic 26%	(-) 20 to (+) 60 D	Monofocal	0°	Clear	
FL260125NY6A	Flex loop	6	12.5	Hydrophilic 26%	(-) 20 to (+) 60 D	Monofocal	0°	Yellow	

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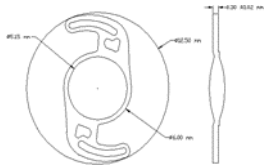
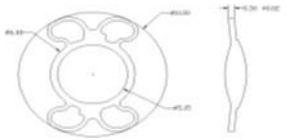
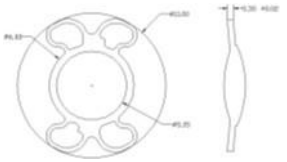
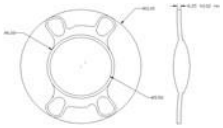
Model Number	Technical parameter								
	Loop	Optic Size	Overall Size	Material	Diopter Range	Optic Design	Haptic Angulation	Color	Picture
FL260125NY5A	Flex loop	6	12.5	Hydrophilic 25%	(-) 20 to (+) 60 D	Monofocal	0°	Yellow	
QL560107EY6A/QL160110EY6A	Quadra	6	11	Hydrophilic 26%	(-) 20 to (+) 60 D	Monofocal	5°	Yellow	
QL560107CR6A	Quadra	6	11	Hydrophilic 26%	(-) 20 to (+) 60 D	Monofocal	5°	Clear	
QL160110NY5A	Quadra	6	11	Hydrophilic 25%	(-) 20 to (+) 60 D	Monofocal	5°	Yellow	

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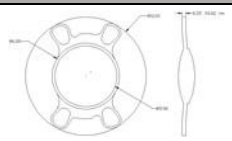
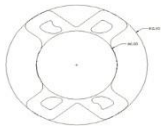
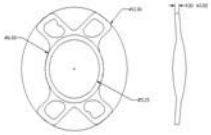
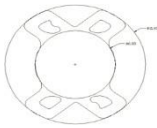
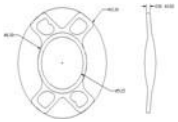
QL160110CR5A	Quadra	6	11	Hydrophilic 25%	(-) 20 to (+) 60 D	Monofocal	5°	Clear	
QL260110CR5A	Quadra	6	11	Hydrophilic 25%	(-) 20 to (+) 60 D	Monofocal	5°	Clear	
QL360110CR6A/AS68,	Quadra	6	11	Hydrophilic 26%	(-) 20 to (+) 60 D	Monofocal	5°	Clear	
QL260110CR6A/AS64	Quadra	6	11	Hydrophilic 26%	(-) 20 to (+) 60 D	Monofocal	5°	Clear	
QL360110NY6A,QL360110EY6A,AS68Y	Quadra	6	11	Hydrophilic 26%	(-) 20 to (+) 60 D	Monofocal	5°	Yellow	

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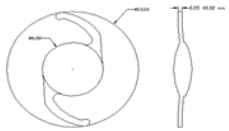
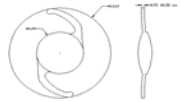
MONOFOCAL HYDROPHILIC ACRYLIC FOLDABLE IOL

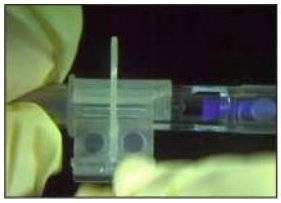
Model Number	Technical parameter								
	Loop	Optic Size	Overall Size	Material	Diopter Range	Optic Design	Haptic Angulation	Color	Picture
LL160130NY5A	L loop	6	13	Hydrophilic 25%	(-) 20 to (+) 60 D	Monofocal	5°	Yellow	
LL160130CR5A, LL160125CR5A	L loop	6	13	Hydrophilic 25%	(-) 20 to (+) 60 D	Monofocal	5°	Clear	

MEDICAL PRELOADED SYSTEM FOR HYDROPHILIC ACRNIC FOLDABLE IOL

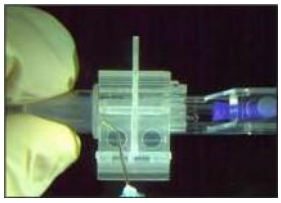
INSTRU CTION FOR USE

Open the blister .and take outthe injector.

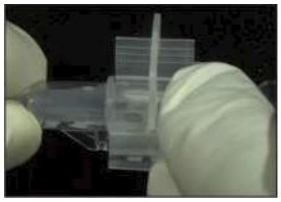
Open the lid of lens container by carefully peeling back the folllid of the lens container. Take out the holder which includes the lens. Do not remove the cartridge coveratthis time.



Place the lens holder over the slot provided in the injector body. Once you hear it “click”, it is securely attached.

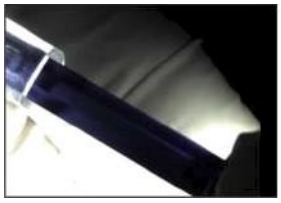


Fill in the viscoelastlc solution into the cartridge tip until Itfloats back into the loading chamber. From the end of the loading chamber, also flll in viscoelastic solution.



Whilst holding the injector horizontally with the nozzle facing away from user, remove the lens holder by lifting up the lower hinge.

Close the loading chamber until its "click lock" mechanism engages. Any resistänce could indicate a trapped IOL.



Press the plunger forward. Continue to push in a .slow and controlled manner. Only push the plunger until the lens has emerged completel'y. Discard the lfiJectorafter use.