

TORIC HYDROPHILIC ACRYLIC FOLDABLE IOL

INSTRUCTION FOR USE

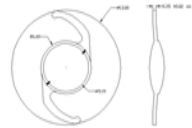
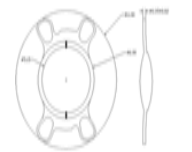
I. INTENDED USE OF THE IOL:

Toric Hydrophilic acrylic foldable intraocular lens 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.

II. DEVICE DETAILS:

Implantable Life Time: -15 years

All our lenses are compatible Lens Delivery System also can come in Single pack depending upon Surgeon's requirement.

Model Number	Technical parameter								
	Loop	Optic Size	Overall Size	Material	Diopter Range	Optic Design	Haptic Angulation	Color	Picture
LL160130NY5Tx	C loop	6.00	13.00	Hydrophilic 25%	(+) 8 to (+) 32 D	Toric	5°	Yellow	
QL160110NY5Tx	Quadra	6.00	11.00	Hydrophilic 25%	(+) 8 to (+) 32 D	Toric	5°	Yellow	

TORIC HYDROPHILIC ACRYLIC FOLDABLE IOL

III. DEVICE DESCRIPTION:

Toric Hydrophilic Acrylic IOL offers combined advantage of Asphericity and Toricity for excellent visual outcome. The IOLs are manufactured from an advanced Polymer of Hydrophilic Acrylic material, UV blocker. {UV Cut off (1 mm Disc) is < 10% @ 360 nm}, and is available in square edge design. The lens is designed to provide clarity for distance vision.

Intraocular Lens (IOL) is an artificial lens that is implanted in the eye to treat Cataract.

Toric intraocular lens known to correct astigmatism, a condition in which eye does not focus light evenly on retina resulting into blurred vision. The curvature of the lens or cornea is noted to be irregular in case of astigmatism which is corrected by toric IOL. The hydrophilic toric IOL is available in natural yellow optic tint which is known to provide better contrast sensitivity by absorbing blue-light.

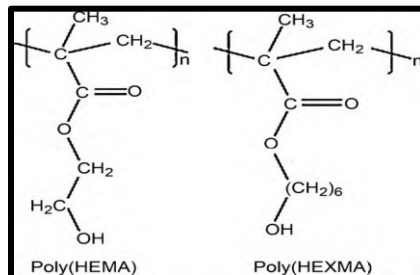
IV. DEVICE MATERIAL DESCRIPTION:

Hydrophilic IOL devices consist of a network of hydrophilic chains that can absorb water, thus also called 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 Di methacrylate (EGDMA), for instance).

In the dry state, these materials are rigid and unfoldable. However, upon water immersion, 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 Toric Hydrophilic Acrylic Foldable IOL contain 25%water content and are available in yellow color.



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

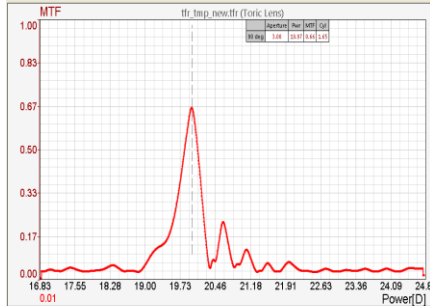
V. DEVICE TECHNICAL SPECIFICATIONS:

- Dioptic Power: (+) 8 to (+) 32 D
- Aspherical power range: -5 to 42 (1.00 to 30.00 with 0.5 increments)
- Cylindrical power range: 0.75 to 6.00
- 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°– 10°

TORIC HYDROPHILIC ACRYLIC FOLDABLE IOL

- Optic material: Hydrophilic Acrylic with 25% water content
- Optic design: Aspheric, Toric, Square edge
- Configuration: Biconvex
- Color: Yellow
- Haptic configuration: Quadra, C loop
- Ref. Index: 1.45-1.50
- % T graph

Modulation Transfer Function (Fig. 1)



VI. MEDICAL INDICATION:

Hydrophilic Toric posterior chamber 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.

VII. 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. The anterior optic contains additional power to offer cylindrical correction from 0.75 to 6.0 D.

VIII. INTENDED USER:

Ophthalmic surgeons only.

IX. TARGET POPULATION:

Aphakic adult patients of age 18 years and above.

X. CALCULATION OF IOL POWER:

The use of methods other than the OSI Toric calculator to select cylinder power and appropriate axis of implantation may not yields similar results. Accurate keratometry and biometry in addition to the use of the OSI Toric Calculator is recommended to achieve optimal visual outcomes.

Toric Hydrophilic Acrylic foldable IOL should not be placed in the ciliary sulcus. Rotation of the Axis toric foldable IOL away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur early as possible prior to lens encapsulation.

XI. 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 you develop your own constant appropriate for you based on clinical experience with the particular IOL models, surgical techniques, measuring equipments and postoperative results.

TORIC HYDROPHILIC ACRYLIC FOLDABLE IOL

XII. METHOD OF STERILIZATION:

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

STERILE

XIII. CLINICAL BENEFIT OF TORIC HYDROPHILIC ACRYLIC FOLDABLE IOL:

Toric IOLs provide a safe and predictable alternative to reduce or eliminate refractive astigmatism with a cylindrical correction, offering patients with preexisting corneal astigmatism optimal distance visual acuity without the use of spectacles or contact lenses.

XIV. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE REFERRED:

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

XV. CONDITIONS OF STORAGE & TRANSPORT:

Toric intraocular lenses are to be stored Store & transport between 5°C to 40°C & Keep away from sunlight.

XVI. RECOMMENDATION FOR CHOOSING LENS DELIVERY SYSTEM:

The use of a lens delivery system is essential for the implantation of the intraocular lens. It consists of a cartridge, injector, and cushion.

All Toric Hydrophilic IOL is supplied in single/Regular pack. Lens Delivery System also can supply in Single pack depending upon Surgeon's requirement.



Cartridge



Injector

XVII. INSTRUCTION FOR THE REMOVAL OF IOL FROM CONTAINER:

Remove IOL vial from peelable pouch. Check the presence of liquid in the vial. 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.

TORIC HYDROPHILIC ACRYLIC FOLDABLE 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 Blister, a leaflet containing diagrammatic representation for handling of preloaded Blister 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.

XVIII. 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.
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	You may want to wear glasses during the daytime hours to prevent anything from touching your

TORIC HYDROPHILIC ACRYLIC FOLDABLE IOL

instructions on how to use them.	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 (used or unused) are classified as medical (clinical) waste that harbors a potential infection or microbial hazard and must be disposed of accordingly

XVIII. 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.

XIX. 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 presents a risk to the sight of the patient. These conditions are (non-exhaustive list):

- Choroidal hemorrhage
- Chronic severe uveitis
- Excessive vitreous loss
- Extremely shallow anterior chamber
- Medically uncontrolled glaucoma & Excessive vitreous pressure
- Microphthalmos

TORIC HYDROPHILIC ACRYLIC FOLDABLE IOL

- 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
- Hemorrhage

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

XX. **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
- Endophthalmitis and Panophthalmitis
- 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 (Ophthalmic solution Inc.) and the competent authority of the Member State in which the user and/or patient is established.

I. **ADVERSE EVENTS REPORTED FROM CLINICAL STUDY:**

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

TORIC HYDROPHILIC ACRYLIC FOLDABLE IOL

II. RESIDUAL RISKS

The finished device is having the Residual Risks such as

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

XXI. 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.
- 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.
- The surgeon must be aware of the risk of opacification of the intraocular lens, which may necessitate IOL removal.
- 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.
All cases of IOL removal must be reported to Ophthalmic solution Inc.

For the Toric intra ocular lenses additional warnings are:

The Physician should consider the following points that are unique to the Toric IOL

- It is recommended emmetropia be targeted for optimum visual performance.
- Patients with significant preoperative or expected postoperative astigmatism > 1.0 D may not achieve optimal uncorrected visual outcomes.
- Care should be taken to achieve Toric centration, as lens decentration may result in a patient experiencing decrease of visual quality under certain lighting conditions.
- As it is the case for all Toric IOLs with simultaneous vision, some patients may experience a reduction of contrast sensitivity compared to monofocal lens (IOL) that may be more important in low lighting conditions.
- Some patients may experience some visual effects due to the superposition of focused and unfocused multiple images at different foci. These visual effects may be perceptions of halos and radial lines around point source of light under night time conditions.

TORIC HYDROPHILIC ACRYLIC FOLDABLE IOL

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

XXII. 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.

XXIII. RETURN GOODS POLICY:

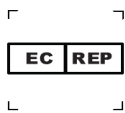
Ophthalmic Solution inc.. accepts returned IOLs for exchanges only in case of manufacturing defect. No cash refunds will be issued. To return IOLs, you must first obtain a Return authorization number from customer services department. No returned goods will be accepted without proper authorization number. 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.

XXIV. 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.

Symbol

information



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THE NETHERLANDS
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Symbol

information



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










Do Not Use If Package Is Damaged or unintentionally opened before use



Do Not re-use

TORIC HYDROPHILIC ACRYLIC FOLDABLE IOL

	Do not resterilize		Keep away from sunlight
	Consult Instructions for Use		Keep dry
	Medical Device		Single sterile barrier system with protective packaging inside
	Authorized Representative in the european community		Sterilized using steam
	Storage Condition between 5°C to 40°C		Manufacturer
	Date of manufacture		Expiry Date
	Sterile Batch No.		Unique device identifier
	Serial number		Model number
	DNV – Notified Body Number		