PRODUCT INFORMATION

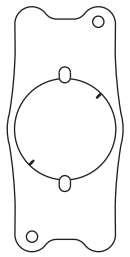
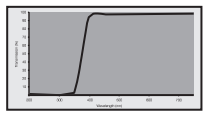
RIL TORIC

Refractive Implantable Toric Foldable Hydrophilic Acrylic IOL

DESCRIPTION OF THE DEVICE

The RIL TORIC (Refractive Implantable Toric lens) is a Phakic intraocular implant manufactured from hydroxyethyl methacrylate (HEMA), with UV blocking properties and biocompatible polymer material. The RIL Toric lens features a plate-haptic design with a central convex/concave with toric optical zone and incorporates a forward vault to minimize contact of the RIL Toric with the central anterior capsule.RIL Toric lenses are capable of being folded and inserted into the posterior chamber through an incision of 2.8 mm or less.

MATERIAL & PRODUCT CHARACTERISTICS

Material Characteristics	IOL Picture
Colour: Clear	
Material : Copolymer of Hydroxy Ethyl Methacrylate and Methyl Methacrylate	
Water Content : 26%	
Refractive Index : 1.46	
YAG Laser Compatible : Yes	
Material spectral Transmittance: 	

RIL MODELS AND DIOPTRIC POWERS

Model Number	Available Dioptric Power(D)	Overall Diameter (mm)	Optic Diameter(mm)	Cylinder Power	Haptic Design
RT1150	-24.0 to +24.0 D	11.50	4.9–5.8	T1 to T10	Flat, plate
RT1175	-24.0 to +24.0 D	11.75	4.9–5.8	T1 to T10	Flat, plate
RT1200	-24.0 to +24.0 D	12.00	4.9–5.8	T1 to T10	Flat, plate
RT1225	-24.0 to +24.0 D	12.25	4.9–5.8	T1 to T10	Flat, plate
RT1250	-24.0 to +24.0 D	12.50	4.9–5.8	T1 to T10	Flat, plate
RT1275	-24.0 to +24.0 D	12.75	4.9–5.8	T1 to T10	Flat, plate
RT1300	-24.0 to +24.0 D	13.00	4.9–5.8	T1 to T10	Flat, plate
RT1325	-24.0 to +24.0 D	13.25	4.9–5.8	T1 to T10	Flat, plate
RT1350	-24.0 to +24.0 D	13.50	4.9–5.8	T1 to T10	Flat, plate
RT1375	-24.0 to +24.0 D	13.75	4.9–5.8	T1 to T10	Flat, plate
RT1400	-24.0 to +24.0 D	14.00	4.9–5.8	T1 to T10	Flat, plate

Sterilization: RILToriclens is sterilized by using moist heat and Disposable Injector Systemis sterilized by using Ethylene oxide (EO).

INDICATIONS

The RILToric is intended to be placed entirely within the posterior chamber directly behind the iris and in front of the anterior capsule of the human crystalline lens when correctly positioned, the lens function as a refractive element to optically reduce moderate to high myopia and hyperopia with astigmatism. The RILToric is indicated for 21-45 years of ageadults.

CONTRAINDICATIONS

- With an anterior chamber depth (ACD)< 2.8 mm
- With anterior chamber angle less than Grade I I as determined by gonioscopic examination.
- Who are pregnant or nursing.
- Who do not meet the minimum endothelial cell density.

WARNINGS

- The long –term effects on the corneal endothelium have not been established. Patients should be advised about potential risk of corneal edema, possibly requiring corneal transplantation.
- The long-term rate of cataract formation secondary to implantation, removal and/or replacement of the RILToricis unknown.
- The potential of the lens to alter intraocular pressure (IOP) and the long-term risks of glaucoma, peripheral anterior synechiae and pigment dispersion are unknown.
- Two basal iridotomies must be performed 90° apart using a YAG laser at least 2 weeks before implantation of thelens, with confirmation of the patency of the iridotomies prior to implantation. The patients should not be taking topical steroid medication at the time of RIL implantation.
- Do Not Resterilize. Resterilization may compromise device performance, which could cause serious harm to the patient's health and safety.
- Do not autoclave the lens. Do not freeze; do not expose to temperature greater than 40 degrees Celsius.
- Single use IOLs and single use injectors cannot be reused, as they are not designed to perform as intended after the first and only usageto avoid infection.
- Do not use after the expiry date.
- Non-toothed, polished instruments must be used if handling the IOL.
- Do not allow the IOL to contact substances that are unsterile or ocular-incompatible prior to placement into the eye.
- Do not use unsterile surgical instruments or instruments that may carry a risk of contamination.
- Once closed with lens, do not reopen the flaps of the injector.

Following implantation, irrigate/aspirate to eliminate any viscoelastic residues from the bag, especially between the IOL and posterior capsule.

Any damage to the peel-pouch or any accidental opening of the peel-pouch is to be declared as "NOT STERILE".

The safety and effectiveness of the RILToric for the correction of moderate to high myopia and hyperopia with cylinder has not been established in patients with:

a) Unstable or worsening myopia and hyperopia
b) A diagnosis of ocular hypertension or glaucoma
c) Pseudoexfoliation
d) Pigment dispersion
e) History or clinical sign of iritis / uveitis
f) Insulin-dependent diabetes or diabetic retinopathy
g) History of previous ocular surgery
h) Progressive sight-threatening disease other than myopia
i) Serious (life- threatening) non-ophthalmic disease

PRECAUTIONS

- Choice of the proper lens size (Model) and Power with cylinder should be carefully considered prior to surgery
- Check the label of the product package for proper lens model,Power, cylinder and expiration date.
- Inspect the blister pack. Ensure that it is not damaged.
- Handle the lens by the haptic portion. Do not grasp the optic with forceps as this could potentially lead to damage to the smooth anterior optical surfaces.
- Never touch the center of the optic with instrument once the lens is placed inside the eye. Inadvertent pressure through the optic could potentially damage the central crystalline lens resulting in a lens opacity.
- AIOpticsPrivate Ltd recommends using AI Optics injector system to insert the RILToric lens in the folded state or use proper injector system to deliver the lenssafely.
- The lens should be carefully examined in the operating room prior to implantation.
- The lensshould not be exposed other than the normally used intraocular irrigating solutions (e.g. isotonic saline, BSS, viscoelastic, etc.)
- Keep the lensmoist, It is recommended that the lens be held in sterile BSS or saline solution prior to implantation.
- The lens should be handled carefully. No attempt should be made to reshape or cut any portion of the lens. Do not apply undue pressure to the lens optical portion with a share object since this could perforate the optic.
- The intended location of the RILToric lens is behind the iris within the posterior chamber and in front of the anterior caspsule of the crystalline lens.
- Complete irrigation and aspiration of viscoelastic from the eye after completion of the surgical procedure is essential. Viscoelastic products that may be difficult to aspirate should not be used.

KEY SURGICAL POINTS

An ECD measurement should be performed preoperatively to determine if candidates meet the minimum ECD requirements based upon age and ACD. Intraocular pressure (IOP) should be checked 24 hours postoperatively. Inadequate flushing of the viscoelastic from the eye may lead to intraocular pressure (IOP) spikes. IOP should be checked 24 hours postoperatively.

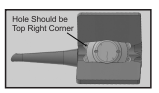
Implantation of any Refractive Implantable Lens should only be attempted by a surgeon who is highly skilled in the required surgical technique.

Inject the lens using appropriate Injection System provided. Verify correct orientation of the RIL Toric lens and that the lens is not inverted. If the pupil remains sufficiently dilated, the lens should be well centered and positioned under the iris in front of the natural lens so that the haptics are placed in the sulcus. Complete aspiration of the viscoelastic material must be performed before the eyeisclosed. From this point the surgeon's standard procedure for postoperative medical care of the patient should be followed.

Physicians requiring information on lens power calculation may contact AI Optics Private Ltd., Customer Service, Email:info@appasamy.com.

IOL LOADING METHOD

This Lens has two Holes. The lens should be placed on the cartridge loading Chamber like one Hole is in the right side of the top (upper) corner and another one is left side bottom corner of the Haptic as shown in the picture.



PATIENT IDENTITY CARD

The packaging contains Patient ID Card for maintaining a record of the IOL implantation. Surgeons are requested to fill the required details and paste the product label and give the filled Patient ID Card to the patient after implantation and advise them to carry the card at all times.

DISPOSAL OF DEVICE

There is No specific guideline for disposing of Non sterile or contaminated / used medical devices. Follow local/national regulations and requirements for discarding outdated or contaminated products.

DISCLAIMER OF LIABILITY

AI Optics Private Ltd., accepts no liability for any Injury happened to patient as result of any improper implantation method or technique used by a physician to implant the lens. AI Optics Private Ltd., makes no expressed or implied warranties in connection with sale and use of the lens for any individual patient without prescription.

RETURN GOODS POLICY

AI Optics Private Ltd accepts returned lenses for exchanges only. No cash refunds will be issued. To return the lens, you must obtain a return authorization number from customer services department. No returned goods will be accepted without proper authorization number. Returned lenses should be shipped by traceable method. No credit will be given to lost or damaged lenses in shipment. Lenses will be replaced as long as they are returned within six months of their original invoice date.

CUSTOMER FEEDBACK AND ADVERSE EVENTS REPORTING

Please report any feedback, adverse events/complaints to AI Optics Private Ltd., 84/1, Aavin Dairy Farm Road, SIDCO Industrial Estate, Ambattur, Chennai - 600098, INDIA. Email: info@appasamy.com.

HOW SUPPLIED

AI Optics Private Ltd.,RIL Toric is supplied with and without Delivery system depends on customer requirement.

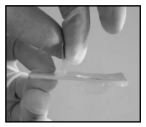
The Package Contains: Foldable Intraocular Lens with Delivery system: One Sterile Intra Ocular Lens, One sterile Lens Delivery system, Patient ID Card, Labels and Information for use (IFU).

Foldable Intraocular Lens without Delivery system: One Sterile Intra Ocular Lens, Patient ID Card, Labels and Information foruse (IFU).

AI Optics Private Ltd.,recommends using our IOL Delivery System for patient's safety. The use of an unqualified Delivery system may cause damage to the lens and potential complications during the implantation process.

If use AI OPTICS qualified Lens Delivery system, please follow the Instruction for use of Delivery system.

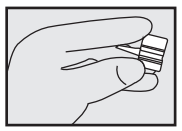
INSTRUCTION FOR OPENING OF PRIMARY PACK



After opening the outer box, examine the device package for any damage, and verify that information (lens model, power, serial number, Expiry Date, etc.) provided on the device primary pack is same as the information provided on the outer box label. Peel the Primary Pack and hold the PP cup in sealing free side by one hand. Slowly peel off the aluminium foil by other hand.

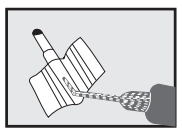
INSTRUCTION FOR USE OF AI OPTICS DELIVERY SYSTEM

STEP : 1



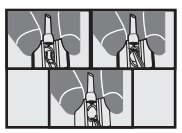
Open the cartridge using thumb and index finger. It is most convenient to load the Lens.

STEP : 2



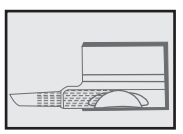
Apply a thin layer of viscoelastic in the lens loading chamber and in the barrel to serve as a lubricant for the free movement of lens through the cartridge during injection. Place the lens into the chamber of the cartridge as described in "IOL loading Method".

STEP : 3



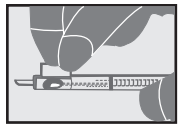
Use flat forceps to gently press the lens and at the same time, partially close the cartridge. Then gently push the haptics and optic to place properly inside the loading chamber and close the cartridge.

STEP : 4



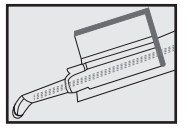
If it is not possible to lock the cartridge, then open the cartridge, remove the lens and reload the lens following steps 2, 3 and 4. Make sure neither the haptic nor optic is caught between the shutters.

STEP : 5



Ensure that there is no gap between the shutters before loading the cartridge into the injector. Load the cartridge into the injector through the groove provided.

STEP : 6



Gently push the plunger until the lens moves towards the cartridge tip. The lens will completely come out of the cartridge.

NOTE

Generally primary viscoelastic used with the RIL Toric lens was a low molecular weight 2% hydroxy propyl methyl cellulose preparation.

- Do not use short chain sodium hyaluronate acids (viscoelastic)

SYMBOLS USED ON LABELING

D	Diopter (Spherical equivalent)
CYL	Cylinder Power
CYL AXIS	Cylinder Axis
IOL	Intraocular lens
STERILE	Sterilized using Steam
	Do not Re-use the product
	Do not Re-sterilize the product
SN	Serial number
	Do not use if package is damaged
5°C 40°C	Store between 5°C to 40°C
	Consult Instructions for use
	Keep away from sunlight
	Keep dry
STERILE EO	Sterilized using Ethylene oxide
	Manufacturer
	Date of Manufacture
	Expiry Date
LOT	LOT Number
REF	Reference (Model) Number
ØB	Optic Diameter of IOL
ØT	Overall length of IOL
	Single sterile barrier system
	Double sterile barrier system
	Caution

Manufacturing Licence No. MFG/MD/2025/000107

Mfgd by:

AI OPTICS PRIVATE LIMITED,
84/1, Aavin Dairy Farm Road,
SIDCO Industrial Estate,
Ambattur, Chennai-600098, INDIA