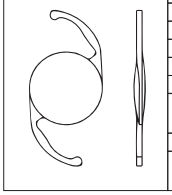
Neo Eye
Hydrophobic Lens

ROHTO

CAUTIONS:
- **PLEASE READ THIS PRODUCT INFORMATION BEFORE USE**
- **THIS DEVICE SHOULD BE USED EXCUSIVELY BY REGISTERED SURGEONS**

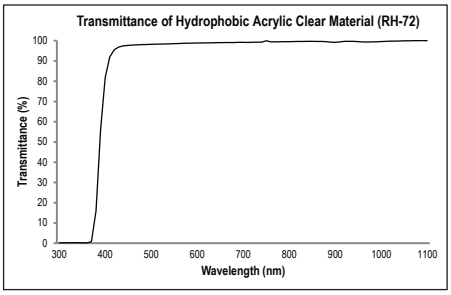
DESCRIPTION
Neo Eye Hydrophobic Lens is a 1-piece Aspheric Intraocular Lens (IOL) with material of hydrophobic acrylic that incorporates polymerizable UV blocker. The lens is designed for folding prior to insertion and gently unfolds to be full size after being inserted and released.

MODEL

Model	Description	Parameter
RH-72	Haptic Design	Modified-C
	Optic Design	Aspheric
	Optic Diameter	6.00 mm
	Overall Diameter	13.00 mm
	Haptic Angulation	0°
	AC Depth	5.20
	A-constant	118.5
	Power Availability	+8.0D to +25.0D (increment of 0.5) +26.0D to +30.0D (increment of 1.0)
	Center thickness	0.35 - 1.10 mm
	Time period limitation for IOL to open in lens capsule	3 minutes

CONTENT
One Sterile Hydrophobic Lens.

MATERIAL CHARACTERISTIC
Hydrophobic acrylic clear material with below characteristic:
- Water content: < 1 %
- ABBE Number: 43
- Spectrum Transmittance:



Spectrum transmittance UV cut-off RH-72 at 10% T is 398 nm

STERILIZATION AND PACKAGING
Neo Eye Hydrophobic Lens is supplied sterile in a polypropylene lens container within a sealed sterilizable Tyvek pouch and terminally sterilized using Ethylene Oxide (EO). The content of the pouch is sterile unless the package is opened or damaged.

A patient card and self-adhesive labels facilitate the patient medical follow-up. These various elements are contained in a cardboard box indicating the usual information (serial number, model of lens, diopter, diagram, and implant information). This card informs the patient about the identity of IOL implanted in case of complications or side effects occurred.

EXPIRY DATE
The expiration date on the packaging is the sterility expiration date.
Sterility is guaranteed unless the pouch or blister is damaged or opened.
Any product held after the expiration date should be returned to ROHTO (refer to RETURNED DAMAGE GOODS POLICY).

USER REQUIREMENT
A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lens.

INDICATIONS
Neo Eye Hydrophobic Lens is indicated for primary implantation in posterior chamber in capsular bag for the visual correction of aphakia, where cataractous lens has been removed by cataract surgery in adult patient.

CONTRAINDICATIONS
Patients with any of the following conditions may not be suitable candidates for an implanting intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient eyesight. Careful preoperative evaluation and sound clinical judgement should be used by the surgeon to decide the benefit-risk ratio before implanting a lens in a patient with one or more of these conditions:
1. Congenital bilateral cataracts
2. Choroidal hemorrhage
3. Concomitant severe eye disease
4. Excessive vitreous loss
5. Extremely shallow anterior chamber
6. Posterior capsular rupture (preventing fixation of IOL)
7. Severe corneal dystrophy
8. Severe optic atrophy
9. Uncontrollable positive pressure
10. Zonular separation (preventing fixation of IOL)
11. Medically uncontrolled glaucoma
12. Chronic severe uveitis
13. Diabetic retinopathy

WARNINGS
1. The potential preoperative complications accompanying intraocular lens implantation may include, but are not limited to the following: anterior vitrectomy, excessive vitreous loss during surgery, expulsive hemorrhage, posterior capsule rupture, iris damage.
2. Implantation of posterior chamber lens in the anterior chamber has been shown to be unsafe and considered as an use-error. The surgeon should explore the use of alternative methods of aphakic correction in these patients and should consider lens implantation only if alternate treatments are deemed unsatisfactory to meet the needs of the patient.
3. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The surgeon must determine the benefits to be derived from lens implantation when such conditions exist.
4. Caution should be used prior to lens encapsulation to avoid lens decentrations or dislocations. Some clinical cases suggest encapsulation occurs within four weeks.
5. It is recommended that viscoelastic solutions should be removed from the eye at the close of surgery with emphasis on the space between the posterior capsule and lens. This may be accomplished by gently depressing the IOL optic posteriorly with the I/A tip and using standard irrigation/aspiration techniques to remove the viscoelastic solutions from the eye. This should force any trapped viscoelastic solutions anteriorly where it can be easily aspirated.

ADVERSE REACTIONS
The following adverse reactions have been reported following cataract extractions and implantation of an intraocular lens may include but are not limited to the following: elevated IOP, retinal detachment, endophthalmitis, posterior capsule opacification, pupillary block, macular edema, hypopyon, IOL dislocation, secondary surgical intervention (iridectomy for pupillary block, vitrous aspiration for pupillary block, repositioning of lens, IOL removal for inflammation, IOL replacement), corneal edema, iritis, secondary glaucoma, synechia, IOL opacification, hyphema, cyclitic membrane formation, viritis, high ametropia and aniseikonia, anterior segment inflammation, atrophy of the iris.

The need for secondary iridectomy for pupillary block maybe prevented by one or more iridectomies at the time of IOL implantation. Secondary glaucoma has been reported occasionally in patient with pre-existing glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively.

Small amounts of lens decentration, occurring with an IOL having a narrow or small optic, may result in a patient experiencing glare or other visual disturbances under certain lighting conditions. Surgeons should consider this potential before implanting an IOL having a narrow or small optic. When implanting a narrow or small optic lens, it is recommended that capsulorhexis be should be performed.

SUGGESTED A-CONSTANT
Preoperative calculation of required for intraocular lens power for these posterior chamber intraocular lenses should be determined by the surgeons experience, preference and intended lens placement. Lens power calculation methods are described in the references below:
- Hoffer, K.J. "The Hoffer Q Formula:A Comparison of Theoretic and Regression Formula". J.Cataract Refract Surg. 19:700-712,1993.
- Holladay, J.T.et.al. "Intraocular Lens Power Calculations for The Refractive Surgeon". J.Cataract Refract Surg. 3:105-117,1998.
- Retzlaff, J.A., Sanders, D.R., and Kraff, M. "Lens Implant Power Calculation". 3rd ed., Slack Inc., Thorofare , N.J., 1990.

The A-constant listed on the outer label is presented as a guideline and is a starting point for implant power calculations.
It is recommended that surgeon develop their own A-constant appropriate for patient based on clinical experience with the lens models, surgical techniques, measuring equipment, and postoperative result.

PRECAUTIONS
1. Check the packaging condition. Do not use the product if the sterile pouch has been opened or damaged.
2. Do not re-use the product. The implication of re-use other than adverse reaction are not clinically well known. Re-use the lens could make infection / complication due to the sterility, quality and properties of re-use lens is not guarantee by ROHTO.
3. Do not re-sterilize the product.
4. Do not rinse the intraocular lens with any solution other than a sterile balanced saline solution or sterile normal saline.
5. Inspect the lens prior to use. Never use the device when anomalies such as damaged, deterioration, deformation or improver operation are found visually.
6. Do not use lens after the expiration date shown on the outside of the package.
7. Product is sterile and must remain in its original package until it is ready to use.
8. Use aseptic technique and remain in a sterile area when handling the lens.
9. Handle lens carefully to avoid damage to lens surface (optic) and/or haptics.
10. If it feels hard when push the plunger on cartridge and disposable injector, re-loading IOL on the cartridge.
11. Forcing an implant though an inadequately enlarged incision results in traumatization of the wound and potentially compromises its ability to self seal.
12. Retrieval lens / disposal lens should be treat following procedure hospital waste management to prevent contamination and returned to manufacturer for treat following procedure handling the retrieval product.

STORAGE
Store in a dry place (min 10°C, max 45°C). Avoid direct sunlight.

DIRECTIONS FOR USE
To avoid breakage, do not attempt to pull the haptics apart, flex the haptics out of the lens or twist/torque the lens.
1. Examine the label on the outer box for model, power, proper configuration, serial number, and expiration date.
2. After the outer box is open, verify the label lens packaging and self-adhesive labels (e.g. model, power, and serial number) is consistent with the information present on the outer box.
3. All instrumentation should be scrupulously clean to minimize the occurrence of marks on the IOL. Any forceps used for lens handling must have round edges and smooth surfaces.
4. Neo Eye Hydrophobic Lens with dioptric power up to +30.0D recommended insertion using Rohto Cartridge and Disposable Injector or other delivery system which have incision size minimum 2.4 mm with fine surface.
5. Under sterile environment and use aseptic technique, remove the lens container from the pouch. Firmly hold lens container in palm of hand and carefully open the lid to expose the IOL.

LOADING TECHNIQUE USING ROHTO CARTRIDGE AND DISPOSABLE INJECTOR MODEL RDI-03
1. Remove the Rohto Cartridge and Disposable Injector from blister packaging in sterile environment and use aseptic technique.
2. Hold the cartridge and fill the cartridge tunnel sufficiently with viscoelastic solution. See Figure 1.
3. Lubricate the IOL with viscoelastic solution. See Figure 2. Carefully grip the haptic with forceps and take out the IOL from its lens container. Do not grip the optical area. The IOL should be handled by the haptic portion only. See Figure 3.
4. Examine the IOL carefully prior to insertion to ensure that particles have not adhered during handling.
5. Insert the IOL into cartridge tunnel, gently push the optic down onto the base of the cartridge. See Figure 4.
6. Fold the trailing haptic over the top of the optic and gently push the IOL with forceps until it is completely in the cartridge. See Figure 5 and 6.
7. The IOL is now in the 'pre-load' position and gently remove the forceps out of the cartridge.
8. Load the cartridge into the injector. See Figure 7 and 8.
9. Push the injector plunger smoothly until it is ready in the cartridge tunnel. Rohto Injector is ready for IOL delivery. See Figure 9. Lens should be injected immediately.
10. Do not store the lens within the cartridge for long period to avoid from sticking.
11. There are various surgical procedures which can be utilized and the surgeon should select a procedure which is appropriate for the patient.

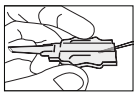
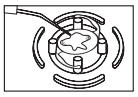


Figure 1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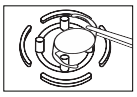
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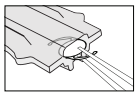
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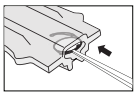
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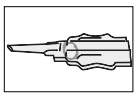
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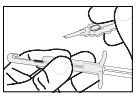
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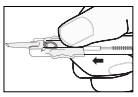
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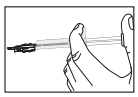
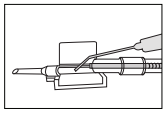


Figure 9

LOADING TECHNIQUE USING ROHTO CARTRIDGE AND DISPOSABLE INJECTOR MODEL RDI-02
1. Remove the Rohto Cartridge and Disposable Injector from blister packaging in sterile environment and use aseptic technique.
2. Hold the cartridge, open the flange of the cartridge sufficient. Apply a generous amount of viscoelastic solution into the nozzle and barrel. See Figure 10.
3. Lubricate the IOL with viscoelastic solution. See Figure 11. Carefully grip the haptic with forceps and take out the IOL from its lens container. Do not grip the optical area. The IOL should be handled by the haptic portion only. See Figure 12.
4. Place the lens in the cartridge on the right position. See Figure 13.
5. Using forceps with fine surface press the lens down and let the flanges close approximately 1/3 to 1/2 way. See Figure 14.
6. Make sure that the haptics are in the correct position. This should secure the haptic and optic in the cartridge. It is imperative that haptics are not twisted. See Figure 15.
7. Remove the fine forceps and close the flanges swift and completely. Make sure that trailing haptic is not straightened out pinched between the flanges. See Figure 16.
8. Push the injector plunger smoothly until it is ready in the cartridge barrel. Rohto injector is ready for delivery. See Figure 17. Lens should be injected immediately.
9. Do not store the lens within the Rohto Cartridge and Disposable for long period to avoid from sticking.
10. There are various surgical procedures which can be utilized and the surgeon should select a procedure which is appropriate for the patient.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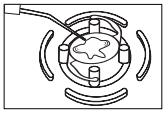
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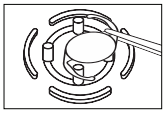
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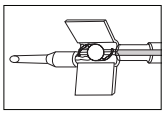
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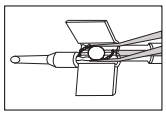
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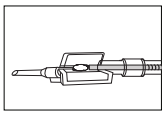
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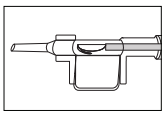
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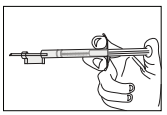
Figure 17

RETURNED DAMAGE GOODS POLICY
Return the lens in its original container identified with the model number, power and reason for return. Do not attempt to re-sterilize the lens.

ISSUED DATE : DECEMBER- 2021

LIST OF SYMBOL USE

SN : Serial Number	: Warning	10°C–45°C	: Store at 10°C to 45°C
: Expiration Date	: For Single Use Only		: See Instruction For Use
STERILE EO : EO Sterilization	: Do Not Re-sterilize		: Manufacturing Date

STERILE

Manufactured by:
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