

**CAUTIONS :**  
 • PLEASE READ THIS INFORMATION BEFORE USE  
 • THIS DEVICE SHOULD BE USED EXCLUSIVELY BY REGISTERED SURGEONS

## DESCRIPTION

**NEO EYE FOLDABLE LENS** is 1-piece Intraocular Lens (IOL) with material of hydrophilic acrylic that incorporates polymerizable UV blocker. The lenses are designed for folding prior to insertion that will gently unfold to its full size after being inserted and released.

## MODEL AND POWER

To allow the surgeon flexibility in meeting individual patient requirements, several distinct types of lenses are available:

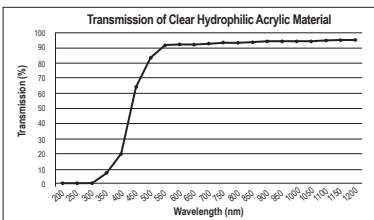
| Model    | Lens Design | Optic Design | Overall Diameter | Optic Diameter | Parameter  |            |
|----------|-------------|--------------|------------------|----------------|--|------------|
|          |             |              |                  |                | Power Availability   | A-Constant |
| RF-22L   |             | Spheric      | 12.5 mm          | 6.0 mm         | -8.0 D to +7.0 D (increment of 1.0 D)<br>+8.0 D to +25.0 D (increment of 0.5 D)<br>+26.0 D to +30.0 D (increment of 1.0 D) | 118.0      |
| RF-31PL  |             | Spheric      | 11.0 mm          | 6.0 mm         | +1.0 D to +7.0 D (increment of 1.0 D)<br>+8.0 D to +25.0 D (increment of 0.5 D)<br>+26.0 D to +30.0 D (increment of 1.0 D) |            |
| RAF-22L  |             | Aspheric     | 12.5 mm          | 6.0 mm         |  |            |
| RAF-31PL |             | Aspheric     | 11.0 mm          | 6.0 mm         |  |            |

**NEO EYE FOLDABLE LENS** presented with 2 types of haptic design, i.e. plate and haptic Modified-C Loop. Both haptic design have stable positioning in the capsular bag. The haptic design provided as surgeon preference and convenience. The optic design of **NEO EYE FOLDABLE LENS** available in spherical and aspherical design. The aspherical design (Model RAF-22L and RAF-31PL) reduce spherical aberration significantly at all pupil sizes up to 6mm. This will increase the night vision.

## MATERIAL CHARACTERISTIC

Hydrophilic acrylic clear material with below characteristic :

- Water Content = 24 - 27 %
- Nd-YAG Laser Compatible
- Spectrum Transmittance :



## SUGGESTED A-CONSTANT

Preoperative calculation of required lens power for these posterior chamber intraocular lenses should be determined by the surgeon's experience, preference, and intended lens placement. Lens power calculation method is 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.
  - Reizlaff, J.A., Sanders, D.R., and Kraft, M. "Lens implant Power Calculation". 3rd ed., Slack Inc., Thorofare, N.J., 1990.
- The A-Constant listed on the outer box label is presented as a guideline and is a starting point for implant power calculations. It is recommended that surgeon developed your own A-Constant appropriate for you based on clinical experience with the lens model, surgical techniques, measuring equipment and post-operative result.

## USER REQUIREMENT

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

## INDICATIONS

**NEO EYE FOLDABLE 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 Small Incision Cataract Surgery (SICS) or phacoemulsification in adult patient.

## CONTRAINDICATIONS

The following are relative circumstances where the surgeon should consider whether implanting an intraocular lens does not create undue risk. Surgeons should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternative are deemed unsatisfactory to meet the needs of the patient.

1. Congenital bilateral cataracts.
2. Cataract in eye with recurrent anterior or posterior segment inflammation.

## 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 Intraocular Pressure (IOP), retinal detachment, endophthalmitis, Posterior Capsule Opacification (PCO), pupillary block, macular edema, hyopyon, IOL dislocation, secondary surgical intervention (iridectomy for pupillary block, vitreous aspiration for pupillary block, repositioning of lens, IOL removal for inflammation, IOL replacement), corneal edema, iritis, secondary glaucoma, synechia, IOL opacification, hyphema, cystic membrane formation, vitritis, high ametropia and aniseikonia, anterior segment inflammation, atrophy of the iris.

The need for secondary iridectomy for pupillary block may be prevented by one or more iridectomies at the time of IOL implantation. Patient with ocular pathology may not achieve the visual acuity and/or may have increased complications compared to patient without such pathology.

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.

Patients who have operative complications should be carefully monitored postoperatively for the occurrence of these complications.

Any serious incident that occurred in relation to the lens implantation should be reported to ROHTO and the relevant authority.

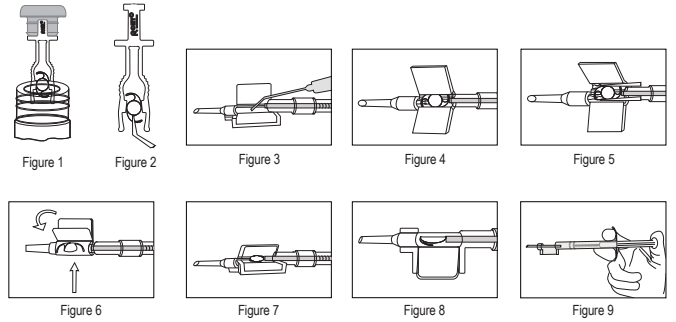
## DIRECTIONS FOR USE

1. Remove the sterile package from the box
2. In a sterile environment, peel off the pouch smoothly and take the IOL out
3. Remove screw cap
4. Take the holder out from the vial carefully. See Figure 1  
 Note : After take out the IOL from the holder, the IOL must be used immediately to avoid dehydration
5. Continue the folding process following Folding Technique Using the Cartridge Injector
6. To minimize of marks on the lens due to folding, all instrument should be scrupulously clean (do not grasp the optical area with forceps)
7. There are various surgical procedure utilized and the surgeon should select a procedure which is appropriate for the patient.

## FOLDING TECHNIQUE USING THE CARTRIDGE INJECTOR

1. Grasp the IOL from lens folder using the non toothed holding-forceps on haptics carefully. See Figure 2.
2. Hold the cartridge, open the flange of the cartridge as wide as possible. Apply sufficient amount of viscoelastic solution into the barrel and cartridge. See Figure 3
3. Place the lens in the cartridge on the right position. See Figure 4
4. Using forceps with fine surface press the lens down and let the flanges close approximately 1/3 to 1/2 way. See Figure 5.
5. 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 5
6. 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 6, 7, and 8
7. Push it all the way to the front, make sure that the tip of the flanges push on the haptic and not on the optic. See Figure 8 and 9  
 Caution : When the lens does not move smoothly in the cartridge, do not start insertion

8. Remove the lens from the cartridge and repeat the folding procedure from the step 1
8. The lens is ready to be injected out through the incision. The lens should be injected immediately
9. There are various surgical procedures which can be utilized and the surgeon should select a procedure which is appropriate for the patient.



**Note :** NEO EYE FOLDABLE LENS is recommended to insert into the eye by using Rohto Cartridge and Disposable Injector or other injector with cartridge tip **minimum 2.4 mm** with fine surface.

## 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 use-error.
3. 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.
4. The viscoelastic should be completely removed after surgery. The remaining of viscoelastic in capsular bag will induce the increase of intraocular pressure.
5. The dye solution should be completely removed after surgery. The remaining of dye solution might cause temporary visual discoloration.
6. Cataract surgery in patient with small eye might be increase the complication post-operatively due to difficulties during surgery.
7. High surgical intervention might increase the complication rate related with endophthalmitis or inflammation. Excessive pushing force and wrong direction during dialing lens in the capsular bag might increase the potential IOL damage.
8. The usage of moxifloxacin drug before intraocular administration should be put cautions that have association with the case of TASS (Toxic Anterior Segment Syndrome).

## PRECAUTIONS

1. Check packaging condition before use. 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 guaranteed by ROHTO.
3. Do not re-sterilize the product.
4. Do not soak or rinse the intraocular lens with any solution other than a sterile balanced saline solution or other sterile saline solution.
5. Inspect lens prior to use. Never use the device when anomalies such as damage, deterioration or improper operation are found visually. The damage lens should be returned to ROHTO.
6. TRANSPORTING FROM COLD TEMPERATURES TO WARM TEMPERATURES MAY CAUSE THE LENS TO CLOUD. DO NOT OPEN OR USE UNTIL THE LENS REACHES THE ROOM TEMPERATURE (AROUND 25°C) AND BECOMES CLEAR.
7. Surgeon should be informed that intraocular tamponade may cause reversible condensation on IOLs before surgery.
8. Because of its hydrophilic properties the IOL can adsorb substance, which it is placed in contact (desinfectants, antibiotics and viscoelastic) may result a "Toxic Lens Syndrome". The IOL must be very thoroughly rinsed by irrigation / aspiration at the end of operation. Patient implanted with this type of IOL must be submitted to particularly careful surveillance.
9. Do not use lens after the expiration date shown on the outside of the package.
10. Product is sterile and must remain in its original package until it is ready to use.
11. Use aseptic technique and remain in a sterile field when handling the lens.
12. FRAGILE, avoid shocks and handle with care.
13. Handle lens carefully to avoid damage to lens surface (optic) and/or haptics.
14. Steam sterilization may leave yellow mild brown stain on lens pouch. This has no impact on sterility of product.
15. 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.

PCO continues to be on of the most common postoperative complications associated with cataract surgery. The square edge design of this IOL creates an effective barrier against PCO and reduces the rate PCO development. However it cannot be excluded, that some patients may experience clinical significant PCO after surgery.

Several reports that almost exclusively in diabetic patients describe the calcification on intraocular lenses in the postoperative period.

## STERILIZATION AND PACKAGING

**NEO EYE FOLDABLE LENS** is supplied sterile in a hydrate state with borate saline solution, packed in vial which is enclosed in a sterile pouch. It was sterilized by steam sterilization.

An implant 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 product package is the sterile expiration date. Sterility is guaranteed unless the pouch is damage or opened. Any product held after the expiration date should be returned to ROHTO (refer to RETURNED DAMAGE GOODS POLICY).

## STORAGE

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

## RETURNED DAMAGE GOODS POLICY

Return the product in its original packaging and identified with the serial number, power and reason for return. Do not attempt to re-sterilize the device.

## ISSUED DATE : DEC - 2022

## LIST OF SYMBOL USE

- |                         |  |                           |
|-------------------------|--|---------------------------|
| : Serial Number         | : Warning                                | : See Instruction For Use |
| : Expiration Date       | : For Single Use Only                    | : Manufacturing Date      |
| : Steam sterilization   | : Do Not Re-Sterilize                    |                           |
| : Store at 10°C to 45°C | : Do Not Use If The Packaging Is Damaged |                           |

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