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Hydrophobic Acrylic Foldable Intra Ocular Lens

Instruction For Use

Description of the IOL: HYDROPHOBIC ACRYLIC FOLDABLE IOL - UV-absorbing {UV Cut off (1 mm Disc) is < 10% @ 360 nm acrylic foldable single-piece posterior chamber IOL is to be implanted for the replacement of human crystalline lens in the visual correction of aphakia in patients with forty years of age and above. The optical portion consists of a high refractive index soft acrylic material. These IOLs have biconvex optics and supporting haptics. This material is capable of being folded prior to insertion. The IOL gently unfolds to a full size IOL body following implantation. The physical properties of these IOLs are:

Material : UV Absorbing Hydrophobic acrylic foldable material
Optic Dia : 5.0 mm to 7.0 mm
Haptic Angle : 0° to 5°
Diametrical : 11.00 mm to 13.50 mm
Colour : Clear/Extended yellow/ Natural yellow
Inner Packing : Single IOL in Lens case, Preloaded (IOL loaded into the injector system)
Outer packing : Single Pack, Combo pack (Single IOL + injector system)

Indication: HYDROPHOBIC posterior chamber intraocular lenses are indicated for the replacement of the human natural lens to achieve visual correction of aphakia in patients with forty years of age and above when extra capsular cataract extraction or phaco emulsification is performed These IOLs are intended for placement in the capsular bag. Implantation of intraocular lens should be done with extra caution in patients under eighteen years of age.

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.

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.

Method of Sterilization:
These posterior chamber intraocular lenses are supplied dry, in a package terminally sterilized with ethylene oxide and must be opened under aseptic conditions.

STERILE | EO

Condition of storage and transportation: Store & transport between 5ºC to 30ºC, protect from direct sun light.

Circumstances under which the IOL can be used: Hydrophobic posterior chamber IOLs are intended to be positioned in the posterior chamber of the eye, after replacing the human natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia.

Instruction for the removal of IOL Pack from container:
i. Examine the label on the unopened package for model, power, configuration, and expiration date.
ii. After opening the cardboard storage container verify the information provided on Pouch/ Lens case/ blister pouch of preloaded system (e.g. model, power and serial number) is consistent with information on outer package labelling.
iii. In case of IOL packed in preloaded system, a leaflet containing diagrammatic representation for handling of preloaded system has been provided separately.

Instruction for Use: (for Single pack and combo pack only):
I. To remove the IOL, open the pouch and transfer the case to a sterile environment. Carefully open the case to expose the IOL. When removing the IOL from the case, DO NOT grasp the optical area with forceps. Prior to the actual folding process, the IOL should be handled by the haptic portion only.
II. Rinse the IOL thoroughly using sterile intraocular irrigating solution (BSS, WFI etc.).
III. There are various surgical procedures, which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.
IV. To minimize the occurrence of marks on the IOL due to folding, all instrumentation should be scrupulously clean.
V. It is recommended to use a forceps with round edges and smooth surface. Surgeons should verify that appropriate instrumentation is available prior to surgery

Note: Prior to insertion the IOL should be carefully examined to ensure that particles have not adhered during handling.

Contents of box:
The packaging contains the sterile product, this instruction for use, the patient card and peelable labels. The peelable labels display the IOL diopter, serial number, model name and model number. 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.

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
- 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
- Rubeosis iridis-Congenital bilateral cataract, recurrent anterior or posterior segment inflammation of unknown etiology, Rubella cataract
- Retinal detachment
- Irdial 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.

Complications:
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

Warnings and Precaution

- Do not re-sterilize these Intraocular Lenses by any methods. If re-sterilized, can cause infection
- Use only sterile intraocular irrigating solution ((BSS, WFI etc.)to rinse and/or soak IOLs to retain sterile condition and avoid contamination
- Do not re-use the IOL. If a 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. Read this instruction for use carefully before implanting an IOL.
- 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 Omni Lens.
- In case of any adverse event noted, contact Omni Lens Pvt. Ltd. without any delay or within 24 hrs. A report describing the adverse event, therapy adopted, traceability detail of the lens used will be requested.
- Omni will not be responsible for any of the damage incurred to patient due to not following above listed warnings. The risks associated are: deterioration of IOL, contamination, infection or loss of vision in operated eye.

Do not use if package is damaged

IOL is void of all warranties expressed or implied if
- IOL is resterilized by any one.
- IOL is repackaged by anyone.
- IOL is altered in any manner.

Expiration Date:
Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the IOL package. Do not use IOL after its expiration date.

Return good policy: Omni Lens Pvt. Ltd. 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.

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