CE 2460

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An ISO 13485 certified company

Hydrophilic Acrylic foldable Intraocular Lens

Instruction For Use

Description of the IOL: Hydrophilic IOL - The ultraviolet absorbing intraocular lenses is implanted for the visual correction of aphakia after removal of natural human crystalline lens in patient with forty years of age and above. The IOLs are manufactured from an advanced Polymer of Hydrophilic Acrylic material, UV blocker. {UV Cut off (1 mm Disc) is < 10% @ 360 nm}The physical properties of these IOLs are:

Material	: Hydrophilic Acrylic
Optic Dia	: 5.0 mm to 7.0 mm
Haptic Angle	: 0 to 10 Degree angle
Diametrical	: 11.00 mm to 13.50 mm
Colour	: Clear/ Extended Yellow/ Natural Yellow
Inner Packing	: Single IOL in glass vial, Single IOL in blister, Preloaded (IOL loaded into the preloaded system)
Outer packing	: Single Pack, Combo pack (Single IOL + injector system)

Indication: Implantation of an intraocular lens may be indicated in the following condition: In conjunction with or following extracapsular cataract extraction in patients with forty year of age or older and who are not good candidate for contact lenses and/or who cannot adapt well to Cataract spectacles. (This may include patients who have occupational limitations). Implantation of the IOL 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: Intraocular lenses are steam sterilized in glass vial contained within a sealed sterilizable pouch. The contents of the pouch/vial are sterile unless the package is damaged or opened.

STERILE

Condition of storage and transport: Store & transport between 5^{o}C to 30^{o}C, protect from direct sun light.

Circumstances under which the IOL can be used: Hydrophilic posterior chamber IOLs are intended to be positioned in the posterior chamber of the eye, after replacing the 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 from container:

- Remove IOL vial from peelable pouch. 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
- 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 aluminium 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 system, a leaflet containing diagrammatic representation for handling of preloaded system 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.

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.

- Grasp the IOL by the loops 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.

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 exercise care in determining 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
- Papillary 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 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.
- All cases of IOL removal must be reported to Omni Lens.

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 information

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the IOL package. Any IOL held after the expiration date should not be used.

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.

EC REP

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