

Method of Sterilization :

Lens Delivery Systems are supplied dry, in a package, terminally sterilized with ethylene oxide and must be opened under aseptic conditions.

STERILE EO

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

Warnings and Precaution:

- Do not re-sterilize these Lens Delivery System by any methods. If re-sterilized, can cause infection
- Do not re-use the Lens Delivery System. If a Lens Delivery System is reused, it can cause loss of vision/serious complication
- Do not use the Lens Delivery System after the expiration date shown on the outside package label. After expiry, sterility is not retained and can cause infection.
- Handle the Lens Delivery System carefully. Rough handling or excessive handling may damage the IOL.
- A high level of surgical skill is required for IOL 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 with use of LDS. Read this instruction for use carefully before implanting an IOL.
- 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 LDS used will be requested.
- Omni will not be responsible for any of the damage occurred 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



Expiration Date:

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated

Return good policy: Omni Lens Pvt. Ltd. accepts returned LDS for exchanges only in case of manufacturing defect. No cash refunds will be issued. To return LDS, you must first obtain a Return authorization number from customer services department. No returned goods will be accepted without proper authorization number. Returned IOL should be shipped by traceable method. No credit will be given to lost or damaged LDS shipment. LDS will be replaced as long as they are returned within six months of their original invoice date.

EC REP

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Issue01_17
Rev01

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Lens Delivery System Instruction For Use

Description of the LDS: Lens Delivery System is a combination of Cartridge, Cushion and Injector
Circumstances under which the Delivery system can be used: Lens Delivery System is a combination of Cartridge, Cushion and Injector, Lens Delivery System is used for the implantation of Foldable intra ocular lenses during cataract operation to minimize the incision size during operation
Instruction for the removal of Lens delivery system from container: Open the pouch and remove the blister pack in sterile environment Thoroughly examine the peel pouch prior to opening to assure sterility
Instruction for Use of Lens delivery system: Follow below Instructions:



Thoroughly examine the peel pouch prior to opening to assure sterility.
Do not use if pouch found damage.



Open the pouch and remove the blister pack in sterile environment.



Take out the Aquaject cartridge from its blister pack in a sterile environment.



Open and hold the flaps in such a way that it is easy to place the lens.

Spread Visco-elastic solution in the barrel and hinge of the cartridge.

Always lubricate the cartridge with Visco-elastic substance.



Place the Foldable IOL in such a manner, that the lens is centered and front haptic pointing left.

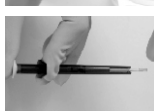


Fold the flaps carefully and inspect the position of the lens in cartridge.

Make sure that back haptic is not trailing and it is not outside the cartridge.

Make sure that haptic & optic is not caught in between the flaps.

Inject some more visco-elastic in the back of cartridge.



Take out the Aquaject injector from its blister pack.

Check the cushion is straight & properly fixed on the tip of the plunger.



Fix the cartridge with properly placed lens on injector by sliding the same in the front slot of injector.

Push the plunger slowly and check whether it glides in the back hole of the cartridge.



Apply the pressure on the plunger for delivering the lens in the bag.

Surgeon should determine the pressure as per their technique, procedure and need.