CE 2460

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LENS DELIVERY SYSTEM

INSTRUCTION FOR USE

I. INTENDED USE OF THE LDS:

Lens Delivery System is a combination of Cartridge, Cushion, and Injector. Lens Delivery System is a single-use and sterile device intended to insert one-piece foldable intraocular lens.

II. DEVICE DETAILS:

There are various models of lens delivery system varying in their cartridge size 2.2mm to 2.4mm. There are different vendors for lens delivery system. All our IOL's are compatible for all our LDS so depending on client's requirement the LDS are provided.

There are models with similar specification but different brands this is due to marketing purpose

Brand Name	Model Name	Raw Material	Cartridge Size	Incision size
Aquaject Plus, LDS,X-Ject	AQ-S-B-Flyglide	Polypropylene	Cartridge size: 2.2 mm	2.2 mm
	AQ-S-B-MJ22		Cartridge size: 2.2 mm	2.2 mm
	AQ-S-B-MJ24		Cartridge size: 2.4 mm	2.4 mm
	AQ-S-B-CON22		Cartridge size: 2.2 mm	2.2 mm
	AQ-S-B-CON24		Cartridge size: 2.4 mm	2.4 mm
	IA-S-B-MD3		Cartridge size: 2.2 mm	2.2 mm
	IA-S-B-MD4		Cartridge size: 2.4 mm	2.4 mm
	IA-S-B-RT3		Cartridge size: 2.2 mm	2.2 mm
	IA-S-B-RT4		Cartridge size: 2.4 mm	2.4 mm

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Compatible model:

Device Sub-category	Model Number	Recommended Compatible LDS model	
		Diopter Range(-) 5 to (+)24.5D	**Diopter Range(+) 25 to (+)45D**
Hydrophilic Foldable Monofocal IOL	CBF32UVA*/UVF600-125A/A20/CBF32UVASP*+/AS62	AQ-S-B-CON22, AQ-S-B-CON24, AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-Flyglide, IA-S-B-MD3, IA-S-B-MD4 , IA-S-B-RT3, IA-S-B-RT4	AQ-S-B-CON24, AQ-S-B-MJ24 IA-S-B-MD4 IA-S-B-RT4
	CBF33UVA*/AS66*/HCL1130606CRA	AQ-S-B-CON22, AQ-S-B-CON24, AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-Flyglide, IA-S-B-MD3, IA-S-B-MD4 , IA-S-B-RT3, IA-S-B-RT4	AQ-S-B-CON24, AQ-S-B-MJ24 IA-S-B-MD4 IA-S-B-RT4
	CBF32UVFLASP*/CBF32UVFL*/UVF600-125FL/HFL1125606CRA	AQ-S-B-CON22, AQ-S-B-CON24, AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-Flyglide, IA-S-B-MD3, IA-S-B-MD4 , IA-S-B-RT3, IA-S-B-RT4	AQ-S-B-CON24, AQ-S-B-MJ24 IA-S-B-MD4 IA-S-B-RT4

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Device Sub-category	Model Number	Recommended Compatible LDS model	
		Diopter Range(-) 5 to (+)24.5D	**Diopter Range(+) 25 to (+)45D**
	YSQFL600ASP*	AQ-S-B-CON22, AQ-S-B-CON24, AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-Flyglide, IA-S-B-MD3, IA-S-B-MD4 , IA-S-B-RT3, IA-S-B-RT4	AQ-S-B-CON24, AQ-S-B-MJ24 IA-S-B-MD4 IA-S-B-RT4
	YSQQ600ASP*/HQL1110606EYA	AQ-S-B-CON22, AQ-S-B-CON24, AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-Flyglide, IA-S-B-MD3, IA-S-B-MD4 , IA-S-B-RT3, IA-S-B-RT4	AQ-S-B-CON24, AQ-S-B-MJ24 IA-S-B-MD4 IA-S-B-RT4
	SQQ600ASP*		
	SQQ600MCR*+/PBF37UVASP*+/AS68/AS64	AQ-S-B-CON22, AQ-S-B-CON24, AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-Flyglide, IA-S-B-MD3, IA-S-B-MD4 , IA-S-B-RT3, IA-S-B-RT4	AQ-S-B-CON24, AQ-S-B-MJ24 IA-S-B-MD4 IA-S-B-RT4
	YSQQ600MCR*+/AS68Y		
	YSQFL600ASP/HFL2125605NYA	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide

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Device Sub-category	Model Number	Recommended Compatible LDS model	
		Diopter Range(-) 5 to (+)24.5D	**Diopter Range(+) 25 to (+)45D**
	YSQQ600ASP/ AY4/LDS AY4/HPL1110605CRA	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide
	SQQ600ASP/HQL1110606CRA		
	PBF37UVASP	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide
	UVF600-130Q	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide

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Device Sub-category	Model Number	Recommended Compatible LDS model	
		Diopter Range(-) 5 to (+)24.5D	**Diopter Range(+) 25 to (+)45D**
	CBFY33SUVASP+/AS66Y/HLL1125605NYA	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide
	SQA600ASP/CBF33SUVASP+/AS66	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide
Hydrophilic Foldable Multifocal IOL	YSQFL600DF/HFL2125605NYD	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide
	YSQQ600DF/M AY4	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4,

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Device Sub-category	Model Number	Recommended Compatible LDS model	
		Diopter Range(-) 5 to (+)24.5D	Diopter Range(+) 25 to (+)45D
			AQ-S-B-Flyglide
	PBFY37MF/HQL1110605NYD	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide
Hydrophilic Foldable Toric IOL	CBFY33UVT#	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide
	PBFY37UVQT#/TAY4	AQ-S-B-MJ22, AQ-S-B-CON22, IA-S-B-MD3, IA-S-B-RT3, AQ-S-B-Flyglide	AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-CON22, AQ-S-B-CON24, IA-S-B-MD3, IA-S-B-MD4, IA-S-B-RT3, IA-S-B-RT4, AQ-S-B-Flyglide
Hydrophobic Foldable Monofocal IOL	LBHF32UVASP/FLL112560CRA	AQ-S-B-CON22, AQ-S-B-CON24, AQ-S-B-MJ22, AQ-S-B-MJ24, AQ-S-B-Flyglide, IA-S-B-MD3, IA-S-B-MD4 , IA-S-B-RT3, IA-S-B-RT4	AQ-S-B-CON24, AQ-S-B-MJ24 IA-S-B-MD4 IA-S-B-RT4
	LBHY32UVASP		
	LBHY33UV		
	CBHF33UVASP		

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Device Sub-category	Model Number	Recommended Compatible LDS model	
		Diopter Range(-) 5 to (+)24.5D	Diopter Range(+) 25 to (+)45D
	PBHF37UVASP/HAY4/H ANY4		

III. DEVICE DESCRIPTION:

The lens delivery system is one of the most effective and useful methods for inserting intraocular lens (IOL) during cataract surgery. In comparison to manual insertion of the lens, IOL implanted using an injector has demonstrated small incision width and higher wound stability1. With the advancements in intraocular lens materials and designs, the concept of dispensing an IOL as pre-packaged, ready-to-insert IOL has been widely adopted by manufacturers2. The primary function of the injector system is to deliver the lens seamlessly into a capsular bag with minimal inflammation and a smaller incision.

A variety of options are available for the user to choose the right injector system such as semi-preloaded or fully pre-loaded delivery systems. This technical documentation consists of a lens delivery system that is supplied with a sterile injector and cartridge set. Parts of the lens delivery system are purchased from different suppliers and are assembled, packaged, and sterilized by Omni Lens Pvt. Ltd.

Cartridge, made of polypropylene, is a device used to hold the lens in place and penetrate the eye for lens implantation. It is available in different sizes with a varying range of tip diameters. The design of the cartridge comprises flaps, guide rail, and the tip.

The function of the guide rail is to hold the lens in place, in a foldable manner if possible. The flaps, also known as wings, ensure the complete fitting of the lens inside the cartridge. The tip penetrates inside the eye for transient time and helps deliver the lens in the capsular bag.

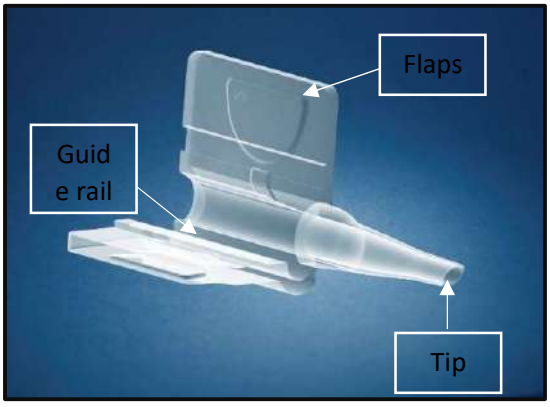


Figure 1.1 Cartridge

Injector primarily consists of the injector body, plunger, and spring as shown in figure 1.2 below. The injector body is an outer body made of ABS (TR) material. And Plunger is made from Poly Carbonate. The function of the plunger is to push the lens forward with the help of the spring attached to it. A flange is designed on the injector body to hold the injector while pushing the plunger. The spring attached to the plunger tip absorbs extra resistance from the force applied through the plunger to enable smooth movement of the lens.

The cushion is a soft silicone rubber that prevents the lens from being damaged when pushed through the plunger. The cushion is placed on the tip of the plunger. Omni Lens Pvt. Ltd. carries out assembling of the cushion into the injector followed by packaging and sterilization of injector and cartridge.

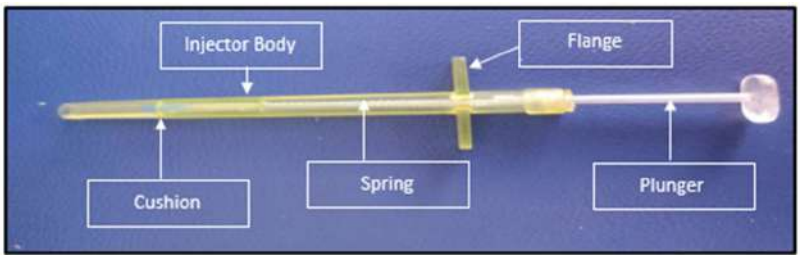


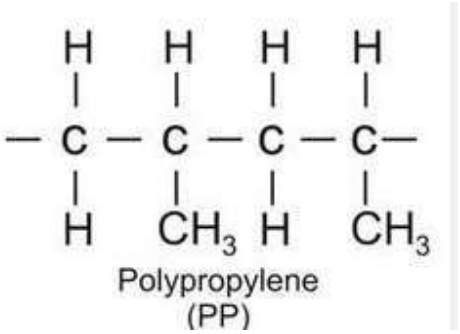
Figure1 .2 Injector Body – Plunger, Spring & Cushion

IV. DEVICE MATERIAL DESCRIPTION:

Components	Raw Material
Cartridge	Polypropylene (randomco-polymer)
Cushion	Silicone (SILASTIC BioMedical Grade Liquid Silicon Rubbers, 7-4860)
Injector	
Injector Body	ABS(TR) (TR557 ABS resin)
Injector Rod (Plunger)	Polycarbonate (LEXAN*)
Spring	Stainless Steel (SS 304)

a. Polypropylene

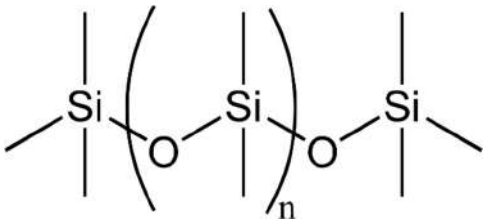
Polypropylene (PP), also known as polypropene, is a thermoplastic polymer used in a wide variety of applications. It is produced via chain-growth polymerization from the monomer propylene. Polypropylene belongs to the group of polyolefins and is partially crystalline and non-polar. Its properties are similar to polyethylene, but it is slightly harder and more heat resistant. It is a white, mechanically rugged material and has a high chemical resistance. Bio-PP is the bio-based counterpart of polypropylene (PP).



Polypropylene is in many aspects similar to polyethylene, especially in solution behaviour and electrical properties. The methyl group improves mechanical properties and thermal resistance, although the chemical resistance decreases.The properties of polypropylene depend on the molecular weight and molecular weight distribution, crystallinity, type and proportion of comonomer (if used) and the isotacticity. In isotactic polypropylene, for example, the methyl groups are oriented on one side of the carbon backbone. This arrangement creates a greater degree of crystallinity and results in a stiffer material that is more resistant to creep than both atactic polypropylene and polyethylene.

b. Silicone

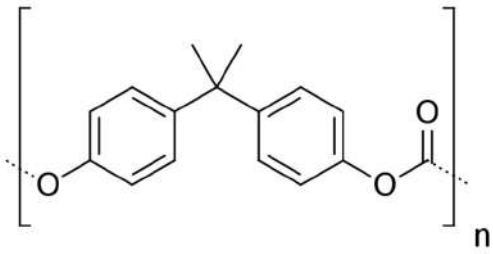
A silicone or polysiloxane is a polymer made up of siloxane (−R2Si−O−SiR2−, where R = organic group). They are typically colorless oils or rubber-like substances. Silicones are used in sealants, adhesives, lubricants, medicine, cooking utensils, thermal insulation, and electrical insulation. Some common forms include silicone oil, silicone grease, silicone rubber, silicone resin, and silicone caulk.



More precisely called polymerized siloxanes or polysiloxanes, silicones consist of an inorganic silicon–oxygen backbone chain (⋯–Si–O–Si–O–Si–O–⋯) with two organic groups attached to each silicon center. Commonly, the organic groups are methyl. The materials can be cyclic or polymeric. By varying the −Si–O− chain lengths, side groups, and crosslinking, silicones can be synthesized with a wide variety of properties and compositions. They can vary in consistency from liquid to gel to rubber to hard plastic. The most common siloxane is linear polydimethylsiloxane (PDMS), a silicone oil. The second-largest group of silicone materials is based on silicone resins, which are formed by branched and cage-like oligosiloxane

c. Polycarbonate

Polycarbonates (PC) are a group of thermoplastic polymers containing carbonate groups in their chemical structures. Polycarbonates used in engineering are strong, tough materials, and some grades are optically transparent. They are easily worked, molded, and thermoformed. Because of these properties, polycarbonates find many applications. Polycarbonates do not have a unique resin identification code (RIC) and are identified as "Other", 7 on the RIC list. Products made from polycarbonate can contain the precursor monomer bisphenol A (BPA).



Polycarbonate is a durable material. Although it has high impact-resistance, it has low scratch-resistance. Therefore, a hard coating is applied to polycarbonate eyewear lenses and polycarbonate exterior automotive components. The characteristics of polycarbonate compare to those of polymethyl methacrylate (PMMA, acrylic), but polycarbonate is stronger and will hold up longer to extreme temperature. Thermally processed material is usually totally amorphous, and as a result is highly transparent to visible light, with better light transmission than many kinds of glass.

d. Stainless Steel

Stainless steel, originally called rustless steel, is any one of a group of ferrous alloys that contain a minimum of approximately 11% chromium, a composition that prevents the iron from rusting and also provides heat-resistant properties. Different types of stainless steel include the elements carbon, nitrogen, aluminium, silicon, sulfur, titanium, nickel, copper, selenium, niobium, and molybdenum. Specific types of stainless steel are often designated by their AISI three-digit number, e.g., 304 stainless.

V. DEVICE TECHNICAL SPECIFICATIONS:

- Incision size of cartridge 2.2 mm to 2.4mm

VI. MEDICAL INDICATION:

All patients who need an implantation of a foldable intraocular lens.

- Vision loss
- Decrease in quality of life
- Depression
- Low visual acuity
- Difficulty in performing visual task

VII. MODE OF ACTION:

Injector/Cartridge (Lens delivery system) is used to deliver the intraocular lens in capsular bag after the cataract surgery.

VIII. INTENDED USER:

Ophthalmic surgeons only.

IX. TARGET POPULATION:

All patients who need an implantation of a foldable intraocular lens.

X. METHOD OF STERILIZATION:

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

XI. CLINICAL BENEFIT OF LENS DELIVERY SYSTEM:

Reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety).

1. Avoidance of potential IOL loading errors
2. Reduced operation time
3. Provided better operating conditions
4. Provide effective and safe IOL delivery
5. provide a clinical improvement in IOL delivery for patients undergoing cataract surgery
6. Gives safe, effective and predictable deliver IOLs in the eye
7. Reducing the potential for lens contamination and postsurgical complications

XII. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE REFERRED:

Link for the availability to SSCP: Link to be provided after notified body acceptance of SSCP.

LENS DELIVERY SYSTEM

XIII. CONDITIONS OF STORAGE & TRANSPORT:

Store & transport between 5^{o}C to 40^{o}C, Keep away from sun light.

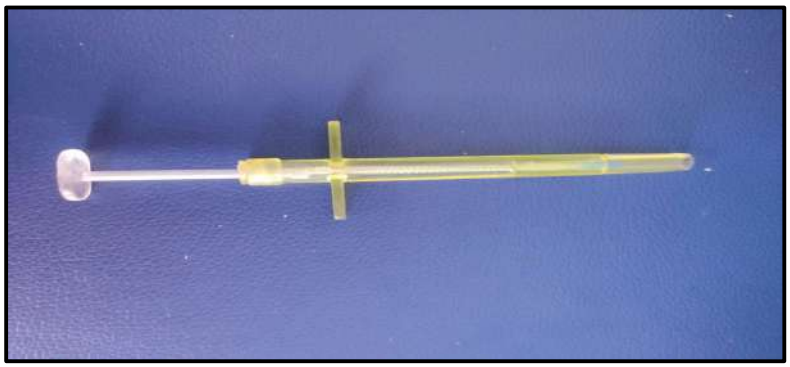
XIV. RECOMMENDATION FOR CHOOSING LENS DELIVERY SYSTEM:

The use of a lens delivery system is essential for the implantation of intraocular lens. It consists of cartridge, injector and cushion.

Lens delivery system is supplied in single/Regular Pack.

Cartridge

LENS DELIVERY SYSTEM



Injector

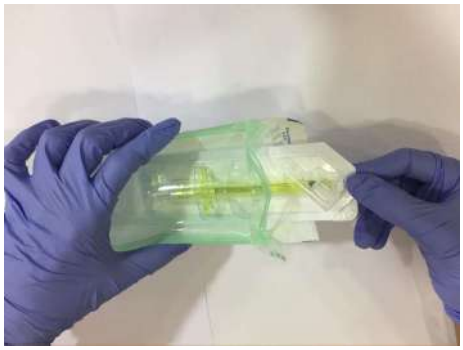
XV. INSTRUCTION FOR USE:

1. Present the package aseptically.

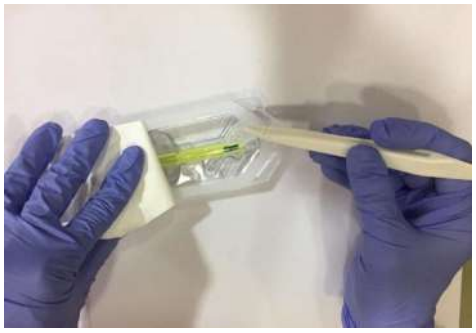
2. Thoroughly examine the peel pouch prior to opening to assure sterility. Do not use if pouch found damage.

LENS DELIVERY SYSTEM

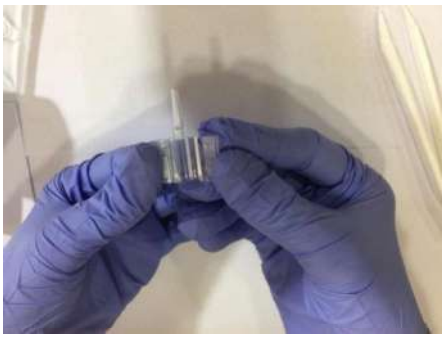
3. Open the pouch and remove the blister pack in sterile environment.

4. Open the blister carefully & take out the cartridge from its blister pack in a sterile environment.

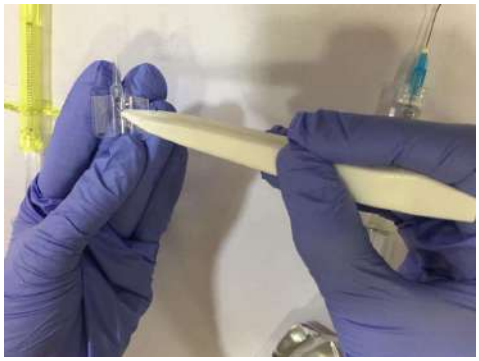
5. Open and hold the flaps in such a way that it is easy to place the lens.



6. Spread visco-elastic solution in the barrel and hinge of the cartridge. Always lubricate the cartridge with viscoelastic substance.

LENS DELIVERY SYSTEM

7. Place the foldable IOL in such a manner that the lens is centred and front haptic pointing left.



8. Fold the back haptic towards optic and try to tuck it under optic.

9. Fold the flaps carefully and inspect the position of the lens in cartridge. You will hear click sound if flaps are correctly closed and nothing is trapped between.
10. Make sure that back haptic is not trailing and it is no outside the cartridge.
11. Make sure that haptic and optic is not caught in between the flaps.

12. Fit the cartridge with loaded lens into the injector properly.

13. Inject some more visco-elastic in the back of cartridge.
14. The lens will slide because of presence of viscoelastic inside the cartridge once lens is in the barrel push the plunger gently and check movement of the lens.

XVIII. CONTENTS OF BOX:

The packaging contains sterile product, instruction for use.

XIX. CONTRAINDICATIONS:

There is no known contraindication for the use of injectors during the implantation of a foldable intraocular lens.

XX. COMPLICATIONS:

- Requirement of additional rotational manipulation of IOL orientation
- Trapped trailing haptic
- Haptic-optic adhesion
- Overriding of plunger over optic

- Trauma to optic edge

I. SIDE EFFECTS/ADVERSE EVENTS REPORTED FROM CLINICAL STUDY:

As with any surgical procedure, there is risk involved. The following non-exhaustive list specifies the complications that have been associated with the implantation of IOLs:
- Potential damage of the eye tissue

II. RESIDUAL RISKS

The finished device is having the Residual Risks such as

- Delivery Failure
- Allergic Reaction

XXI. WARNINGS & PRECAUTIONS:

- Do not re-sterilize these lenses 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 if package is damaged or unintentionally opened before use
- 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.
- Reporting to manufacturer for adverse event. In case of any adverse events noted, contact manufacturer (Omni Lens Pvt. Ltd.) or authorized representative and competent authority of the member state where user/ patient is established 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 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.

XXII. EXPIRATION DATE INFORMATION:

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

XXIII. RETURN GOODS 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 LDS 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.

XXIV. DISPOSE OF USED MEDICAL DEVICE CONTAINER/PACKAGE:

- Do not dispose damaged or explanted device or its packing with household trash. Disposal of devices and its packaging is considered a biohazard. Follow local regulatory guidelines for disposing off devices and it's packaging safely.
- Put used device package in disposal container as per your community guidelines for the right way to dispose of your disposal container.
- You may use a household container that is: made of a heavy-duty plastic, can be closed with a tight-fitting, puncture-proof lid, without sharps being able to come out, upright and stable during use, leak resistant, properly labelled to warn of hazardous waste inside the container.
- When your disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your disposal container. There may be state or local laws about how you should throw away used device package.
- Do not recycle your used sharps disposal container

XXV. OPERATIONAL PROCEDURE

- The appropriate surgical techniques are the responsibility of the respective surgeon. He or she must assess the appropriateness of the relevant procedure based on his or her education and experience.
- Further the manufacturer guarantees that this product is compatible with the manufacturers model produced and listed in the table below.
- The manufacturer is not liable for any issues, complaints defects occur if the user deliberately uses the lens delivery system is used with any other device not listed in the compatibility chart below.

XXVI. GUARANTEE AND LIMITATION OF LIABILITY

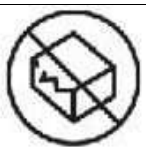
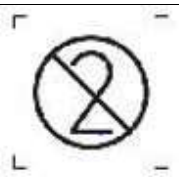
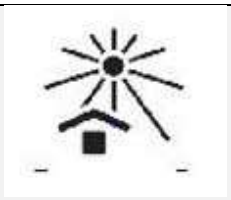
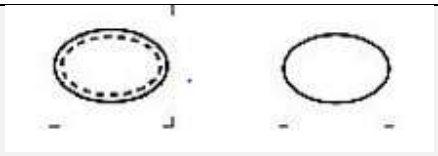
- The manufacturer guarantees that this product was produced with appropriate care and shall assume no responsibility for incidental or consequential damages, losses or costs that should result directly or indirectly from the use of this product.
- Liability is solely limited to claim-related repairs that must be performed on the product which are clearly not attributed to incorrect handling or the use of lenses not validated for this injector model.

CE 2460

An ISO13485 certified company

LENS DELIVERY SYSTEM

Omni Lens Pvt. Ltd. A-69/A-70, Electronic Estate, GIDC, Sector-25, Gandhinagar-382016, Gujarat, India. **Reg. office:** 5, Samruddhi, Opp. Sakar III, Navarangpura, Ahmedabad-380014, Gujarat, India. Email: info@omnilens.in	EC REP Obelis S.A. Boulevard General Wahis 53 1030, Brussels, Belgium Tel: +(32)2. 732.59.54 Fax: +(32)2. 732.60.03 Email: mail@obelis.net

 Do Not Use If Package Is Damaged or unintentionally opened before use	 Do Not re-use
 Do not resterilize	 Keep away from sunlight
 Consult Instructions For Use	 Keep dry
 Medical Device	 Single sterile barrier system with protective packaging insideor Single sterile barrier system

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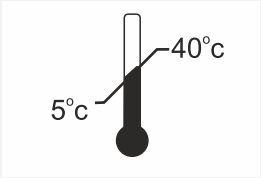
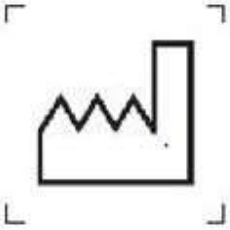
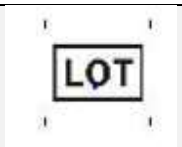
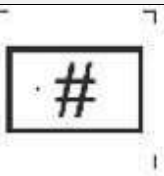
LENS DELIVERY SYSTEM

 Authorized Representative in the European community	 Sterilized using ethylene oxide
 Storage Condition between 5°C to 40°C	 Manufacturer
 Date of manufacture	 Expiry Date
 Sterile Batch No.	 Unique device identifier
 Serial number	 Model number