LENS DELIVERY SYSTEM (LDS)

INSTRUCTION FOR USE

I INTENDED PURPOSE OF THE LDS:

Lens Delivery System (LDS) is a combination of Injector, Cushion, and Cartridge. 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, 2.4mm to 2.8mm. All our IOL's are compatible with all our LDS, so depending on client's requirement the LDS are provided along with the Foldable IOL.

There are models with similar specifications but different brands, this is due to marketing purposes.

Raw material	Cartridge Size	Incision Size
Poly propylene	Cartridge size: 2.2 mm	2.2 mm
	Cartridge size: 2.4 mm	2.4 mm
	Cartridge size: 2.8 mm	2.8 mm

Product Name	Diameter	Length	Locking Length	Plunger Diameter	Pusher Diameter	Pusher Length
EXCEL Jet	8.00 mm	140 mm	15.80 mm	1.30 mm	2.50 mm	9.50 mm
EXCEL Jet Pro	8.00 mm	140 mm	15.80 mm	1.30 mm	2.50 mm	9.50 mm
EXCEL Jet Pro+	8.00 mm	140 mm	15.80 mm	1.30 mm	2.50 mm	9.50 mm

III DEVICE DESCRIPTION:

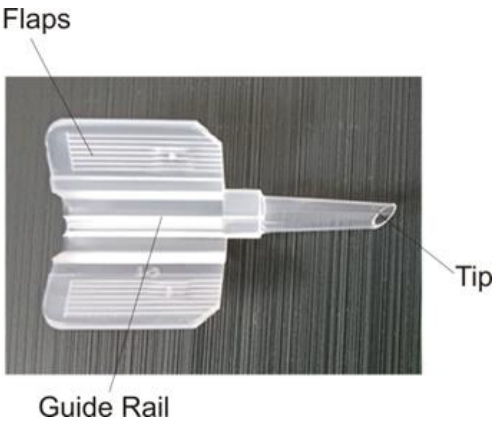
The lens delivery system is one of the most effective and useful methods for inserting intraocular lens (IOL) during cataract surgery. In comparison to manual insertion of the lens, IOL implanted using an injector has demonstrated small incision width and higher wound stability. With the advancements in intraocular lens materials and designs, the concept of dispensing an IOL as pre-packaged, ready-to-insert IOL has been widely adopted by manufacturers. 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 Excel Optics (P) Limited.

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.



Injectors primarily consists of the injector body, plunger, and spring as shown in figure 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. Excel Optics (P) Limited., carries out assembling of the cushion into the injector followed by packaging and sterilization of injector and cartridge.

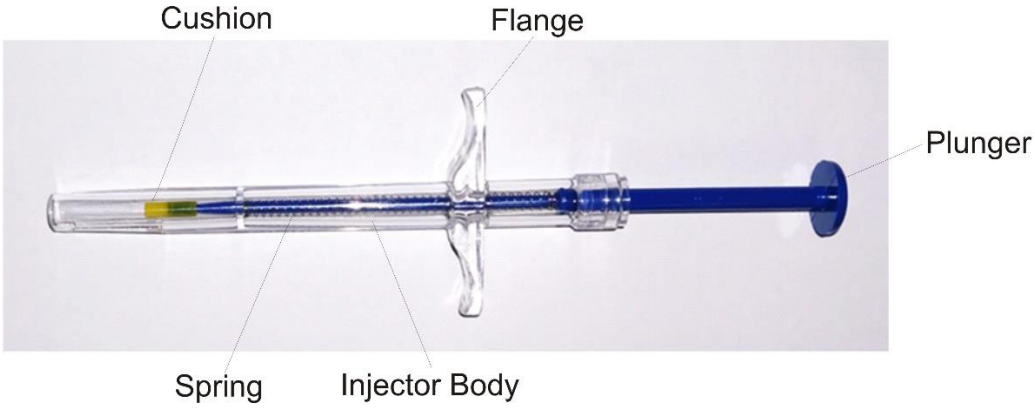


Figure. Injector Body – Plunger, Spring Cushion

LENS DELIVERY SYSTEM (LDS)

IV. DEVICE MATERIAL DESCRIPTION

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

V DEVICE TECHNICAL SPECIFICATIONS:

- Incision size of cartridge 2.2 mm ,2.4 mm & 2.8 mm

VI MEDICAL INDICATION:

All patients need an implantation of a foldable intraocular lens.

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

VII MODE OF ACTION:

Injector/Cartridge (Lens delivery system) is used to deliver the intraocular lens in capsular bag during 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 (LDS) 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

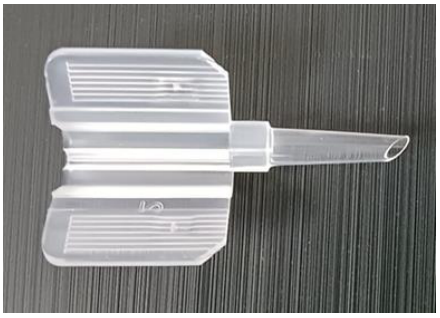
XII CONDITIONS OF STORAGE & TRANSPORT:

Store & transport between 5ºC to 40ºC, Keep away from sun light.

XIII RECOMMENDATION FOR CHOOSING LENS DELIVERY SYSTEM:

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

Lens delivery system is supplied in single/Regular Pack.



Cartridge

Injector

XIV. INSTRUCTION FOR USE:

LENS DELIVERY SYSTEM (LDS)

Intraocular Lens
INJECTING TECHNIQUE

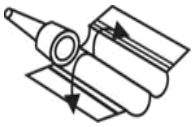


Fig.01

1. The Cartridge is to be opened 180° open position for most suitable position for loading the Lens.

2. Apply a thin layer of Viscoelastic in the lens loading chamber and a very small amount in the barrel and hinge will serve as a lubricant for the free movement of lens during the injection process**.**

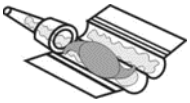


Fig.03

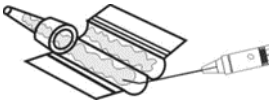


Fig.02

3. After the lens is well placed I the cartridge, ensure that it is correctly centered (Pl. See Fig.03)

4. Applying a few drops of BS solution on the surface of the lens, as in Fig.04,will help to keep the lens in hydrated condition.As the lens is Hydrophilic in nature, this is helpful.

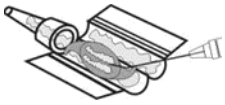


Fig.04

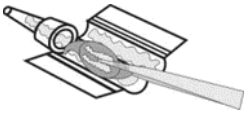


Fig.05

5. Using Flat Forceps gently press the center of the lens and at the same time closes the cartridge without pinching the loop or the sides of the optic.

6. Make sure neither the haptic nor the optics is caught in between the shutters (if it happens some gap will be observed between the shutters after closing the cartridge) as shown in Fig.06.If the gap is observed, repeat step no. 3,4 & 5.

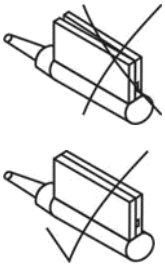


Fig.06

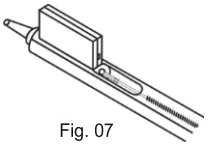


Fig. 07

7. Load the cartridge into the injector as shown in Fig .07 only if there is no gap between the shutters.

Recommendation: Do not push the plunger tip forcefully till the end of Cartridge - as shown in Fig.08.It may damage the cartridge and lens.

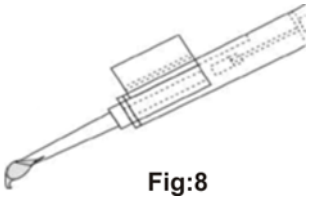
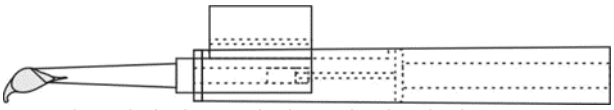


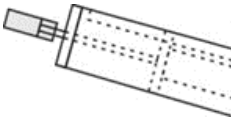
Fig:8

Note: Pushing the plunger tip till the end of cartridge tip is not necessary to deliver the lens. While pushing if you feel any resistance release the thumb and take the lens out. Immense the lens in BSS solution. Again reload the lens as per step no. 3,4 &5



8. Gently push the lens and release the thumb, the same action can be repeated until the lens moves towards the cartridge tip end – as shown in Fig.09.

9.Gently release the thumb pressure given to plunger, when 80% of the lens is out.The Plunger will automatically come back, and at the same time the lens will pull itself out from the cartridge.If required, small push may be given to get the lens out fully.To avoid rotating of Lens while it is coming from the cartridge the lens has to be properly loaded in center of cartridge and near by barrel area.



Applicable for soft disposable tip Injectors only

Disposable tip has asoft silicone sleeve attached to one end of the plunger tip.

Hold the silicone covered end and insert the other end in to the tip of the plunger and straighten it tightly.

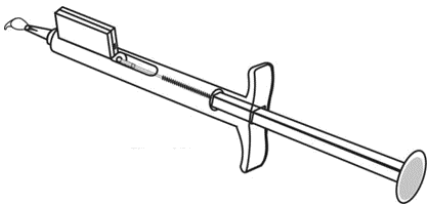


Fig.10

LENS DELIVERY SYSTEM (LDS)

XV CONTENTS OF BOX:

- The packaging contains sterile products and instructions for use.

XVI CONTRAINDICATIONS:

- There is no known contraindication for the use of injectors during the implantation of a foldable intraocular lens. Since this LDS is an accessory to foldable IOL, physician should carefully read the contraindication for the IOL being implanted and follow the instruction completely.

XVII COMPLICATIONS:

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

I A 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

I B RESIDUAL RISKS

The finished device is having the Residual Risks such as

- Delivery Failure
- Allergic Reaction
-

XVIII WARNINGS & PRECAUTIONS:

- Do not re-sterilize these lenses Delivery System by any method. 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 (Excel Optics (P) Limited.,) or authorized representative and competent authority of the member state were user/ patient.
- It 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.
- Excel Optics will not be responsible for any of the damage that 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.

XIX EXPIRATION DATE INFORMATION:

LENS DELIVERY SYSTEM (LDS)

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

XX **RETURN GOODS POLICY:**

Excel Optics (P) Limited 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 the customer services department. No returned goods will be accepted without a proper authorization number. Returned LDS should be shipped by traceable method. No credit will be given to lost or damaged LDS shipments. LDS will be replaced if they are returned within six months of their original invoice date.

XXI **DISPOSE OF USED MEDICAL DEVICE CONTAINER/PACKAGE:**

- Do not dispose of damaged or explanted device or its packing with household trash. Disposal of devices and their packaging is considered a biohazard. Follow local regulatory guidelines for disposing of devices and their 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 packages.
- Do not recycle your used sharps disposal container.

XXII **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.

XXIII **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.

LENS DELIVERY SYSTEM (LDS)

Symbols and their explanations

EC REP	Authorized Representative in the European community	SN	Serial Number
STERILE EO	Sterilized using Ethylene Oxide		Do not re-sterilize
40°C 5°C	Storage Condition between 5°C to 40°C		Keep away from sunlight
	Manufacturer		Consult Instructions for Use
LOT	Sterile Batch No		Keep Dry
UDI	Unique device identifier	MD	Medical Device
	For Cartridge - Single sterile barrier system		For Injector - Double sterile barrier system
#	Model Number		use- by date
	Do not Use If package is Damaged		Date of Manufacturer
IN	Country of Manufacture	AC PC	
UV	Ultraviolet		Do Not re-use
	Caution		

EC REP **MED DEVICES LIFESCIENCES B.V.**
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