

# MULTIDIFF TRIFIT

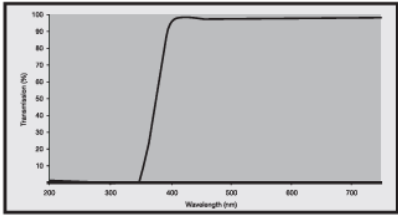
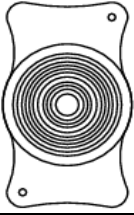
## Foldable Hydrophilic Acrylic Intraocular Lens

### DESCRIPTION OF THE DEVICE

The Multidiff Trifit sterile UV-absorbing Hydrophilic foldable single piece posterior chamber lens is an optical implant for the replacement of human crystalline lens in the visual correction of aphakia.

Multidiff Trifit is available in variable diopters ranging from 0 to 35 diopters with the increment of 0.5 D which are inspected by higher end laser interferometers. These lenses have four point supporting haptics for easy centration and aspherical surface on posterior side and Refractive-Diffractive surface on anterior surface. This feature helps to the patient for reading without spectacle. Multidiff Trifit provides clear vision for distance, intermediate and near. The add power for near vision is +3.5D and for the intermediate vision it is +1.65D.

### MATERIAL AND PRODUCT CHARACTERISTICS

<b>Material Characteristics</b>	
<b>Model</b>	<b>MFDY705</b>
Colour	Clear
Material	Copolymer of Hydroxy Ethyl Methacrylate and Methyl Methacrylate
Water content	26%
Refractive Index	1.46
Minimum Resolution Efficiency	70%
YAG Laser Compatible	Yes
Light Transmittance	
<b>Product Characteristics</b>	
<b>Model</b>	<b>MFDY705</b>
Optics Design	Single Piece Equi-biconvex with diffractive anterior surface
Haptic Design	Plate Haptic
Drawing	
Optic Diameter	6.00 mm
Overall Length	11.00mm
Power Range	0.0D to 35.0D (In steps of 0.5D)

### INTENDED USE

It is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. It provides clear vision at both near and far.

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### INDICATIONS

IOL indicated for the replacement of the human lens to achieve visual correction of aphakia following cataract (Monocular cataract or Mature cataract or congenital cataract or Occupational needs or traumatic or senile cataract) surgery. These lenses are intended for placement in the capsular bag.

### CONTRAINDICATIONS

- Chronic Severe Uveitis
- Epithelial Dystrophy
- Proliferative Diabetic Retinopathy
- Choroidal Haemorrhage
- Microphthalmos
- Concomitant Severe Eye Disease
- Glaucoma Problem
- Rubella Cataract
- Massive Vitreous Loss
- Anirida

### DEVICE INTENDED USER:

Ophthalmic surgeon

### TARGET POPULATION:

- The device is primarily recommended for adults aged 18 years(Male or Female) and older with stable ocular anatomy.
- **Pediatric Use:** Use in infants or children below 18 years is a clinical decision that must be made by the surgeon based on a dedicated risk-benefit analysis of the individual patient's condition.

### Link for SSCP:

<https://www.appasamy.com/ai-optics>

### RESIDUAL RISKS

- 1.Vision Loss
- 2.Inflammation, Optic Decentration, Posterior Capsule (PC) Rent
- 3.Wound Leakage, Corneal Edema, Blurred Vision, Toxic anterior segment syndrome

### POTENTIAL HAZARDS

The relevant hazards and side effects of Intra Ocular lens essentially the same as (but not limited to) those of routine cataract extraction. These include the following:-

- Intra Ocular Foreign Body Debris
- Temporary Corneal Edema

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- Secondary cataract formation
- Vitreous Herniation into the formation
- Malpositioned Lens
- Aphakic Glaucoma
- Temporary Flat Anterior Chamber
- Retinal Detachment
- Lens Implants Loop Amputation
- Endothelial Corneal Dystrophy Anterior Chamber Infection
- Pupillary Block
- Corneal Dystrophy
- Posterior capsular opacification

If product is used for Cataract in patients below age of 18 years the following complications may occur:

- Amblyopia
- Risk of glare and halos
- Visual axis opacities due to inflammation or tissue growth
- Reading acuity
- Squint

The manufacturer has pursued the clinical literatures and risk management activities and finally came out with a risk-benefit analysis for the clinical decision making.

Hence the final clinical decision for the infants/children below 18 shall be made by the ophthalmologist based on risk based benefit analysis based on the clinical conditions.

### **WARNINGS**

1. Do Not Resterilize. Resterilization may compromise the device performance, which could cause serious harm to the patient's health and safety.
2. Do not store below 5°C and above 40°C to avoid shocks & fragile.
3. Lens should not be altered in any manner.
4. Lens should not be repackaged by anyone.
5. Single use IOLs and single use injectors cannot be reused, as they are not designed to perform as intended after the first and only usage to avoid infection.
6. Do not use after the expiry date.
7. Non-toothed, polished instruments must be used if handling the IOL.
8. Do not allow the IOL to contact substances that are unsterile or ocular-incompatible prior to placement into the eye.
9. Do not use unsterile surgical instruments or instruments that may carry a risk of contamination.
10. Do not allow the IOL to dehydrate during the procedure.
11. Once closed, do not reopen the flaps of the injector.
12. Following implantation, irrigate/aspirate to eliminate any viscoelastic residues from the bag, especially between the IOL and posterior capsule.

### **CALCULATION OF LENS POWER**

Accurate Keratometry and biometry is essential to successful visual outcomes. Preoperative calculation of the required lens power for these posterior chamber intraocular lenses should be determined by the surgeon's

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experience, preference, and intended lens placement. The A-constant listed on the outer label is presented as a guideline and is a starting point for implant power calculations. This provisional A- constant has been theoretically derived. Lens constants must be “Personalized” to compensate for the differences in instrumentation, measurement technique, and IOL power calculation methods. A convenient initial estimate can be obtained by referencing to the personalized lens constant for a similar lens model.

### **DISCLAIMER OF LIABILITY**

AI Optics Private Limited accepts no liability for improper model selection by the physician, for improper handling, use, surgical technique applied or for any other iatrogenic error caused by the implanting surgeon. AI Optics Private Limited makes no expressed or implied warranties in connection with sale of the IOL.

### **‘A’ CONSTANT**

'A' Constant Value is to be provided on the box cover label. This number is given only as a guideline and not based on any clinical data. It is advised that the surgeon calculates his own value for each style and specifications of Intra Ocular Lens.

### **STERILIZATION**

Sterilization is done By Moist Heat Sterilization Method. Validity of sterilization applies as long as the sealed peel-pouch is not disturbed or damaged. Any damage to the peel- pouch or any accidental opening of the peel-pouch is to be declared as “NOT STERILE”.

### **DIRECTION FOR USE**

PLEASE examine the peel-pouch prior to opening to assure sterility. Any Damage to the peel-pouch should be viewed very seriously and the IOL inside might not be sterile. After proper examination, peel the pouch and remove the PP Cup carefully. Hold the PP Cup and peel aluminum seal. Lift the PP Cup seal up to expose the IOL. Please NEVER soak or rinse the IOL in solutions. Do not use rubber gloves dusted with talc powder. It may cause irritation.

### **REPORTING**

Adverse reactions and potentially sight threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature severity or degree of incidence should be reported to AI Optics Private Limited. This information is requested from the all implanting surgeons in order to document potentially long term effects of IOL implants.

### **PATIENT IDENTITY CARD**

The packaging contains product identification stickers(labels) to paste on the patient record & patient ID card for maintaining the record of the IOL implantation for maintaining a record of the IOL implantation. Surgeons are requested to give the “Patient ID Card” to the patient after implantation and advise them to carry the card at all times.

### **RETURN GOODS POLICY**

AI Optics Private Limited accepts returned lenses for exchanges only. NO cash refunds will be issued. To return lenses, you must obtain a return authorization number from customer services department. No returned goods

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will be accepted without proper authorization number. Returned lenses should be shipped by traceable method. No credit will be given to lost or damaged lenses in shipment. Lenses will be replaced as long as they are returned within six months of the original invoice date.

### CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

### DISPOSAL OF IOL

The intended disposal of an intraocular lens should be safe and effective way. The IOL at an end of life or explants of faculty; defective or opened in unsterile environment or due to mishandling or any other reason the product is not possible to implant should be discarded into the waste and comply with the local health & safety requirements.

### HOW SUPPLIED

AI Optics Private Limited IOLs are supplied with Delivery system depends on customer requirement.

#### The Package Contains

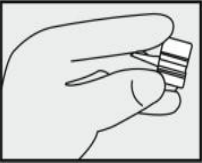
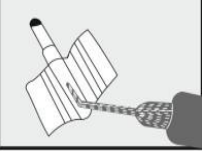

One Sterile Intra Ocular Lens, One sterile Lens Delivery system, Patient ID Card, Labels and Information for use (IFU).

AI Optics Private Limited recommends using IOL Delivery System provided with our IOL for patient's safety. The use of other Delivery system may cause damage to the lens and potential complications during the implantation process.

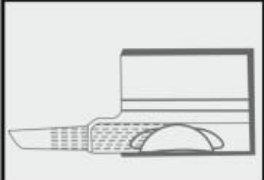
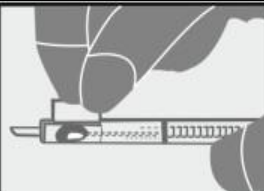
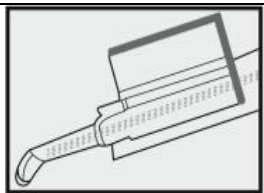
If using AI Optics Private Limited Lens Delivery system provided with our IOL, please follow the "Instruction for Use of Delivery System."

**NOTE:** To avoid dehydration, leave the lens as immersed in saline until ready to fold and implant. The lens should be folded and implanted within 3 minutes after removal from the saline.


















### INSTRUCTION FOR USE OF DELIVERY SYSTEM

	<p><b>STEP:1</b> Open the cartridge using thumb and index finger. It is most convenient to load the lens.</p>
	<p><b>STEP:2</b> Apply a thin layer of viscoelastic in the lens loading chamber and in the barrel to serve as a lubricant for the free movement of lens through the cartridge during injection. Since the lens has square edge on its posterior side, place the lens in the loading chamber of the cartridge to ensure that posterior side of the lens face downwards.</p>
	<p><b>STEP:3</b> Use flat forceps to gently press the lens and at the same time, partially close the cartridge. Then gently push the leading and trailing haptic over the optic and close cartridge.</p>





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	<p><b>STEP:4</b>          If it is not possible to lock the cartridge, then open the cartridge, remove the lens and reload the lens following steps 2, 3 and 4. Make sure neither the haptic nor optic is caught between the shutters.</p>
	<p><b>STEP:5</b>          Ensure that there is no gap between the shutters before loading the cartridge into the injector. Load the cartridge into the injector through the groove provided.</p>
	<p><b>STEP:6</b>          Gently push the plunger until the lens moves towards the cartridge tip. The lens will completely come out of the cartridge.</p>

**SYMBOLS USED ON LABELING**

<b>D</b>	Diopter(Spherical equivalent)
<b>IOL</b>	Intraocular lens
	Sterilized using steam or dry heat
	Do not re-use
	Do not re-sterilize
	Serial number
	Do not use if package is damaged
	Store between 5°C to 40°C
	Instructions for use
	Keep away from sunlight
	Keep dry
	Sterilized using Ethylene oxide
	Manufacture
	Date of Manufacture
	Expiry
	LOT Number
	Reference (Model) Number
$\varnothing_B$	Optic Diameter
$\varnothing_T$	Overall Length
	Single sterile barrier system
	Double sterile barrier system

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	Caution, Consult
	Medical Device
	CE conformity Marketing and the Notified body number
	Authorized Representative in the European Community/European Union

Manufacturing License No. MFG/MD/2025/000107

**Manufacturer by:**



**AI OPTICS PRIVATE LIMITED,**

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