STERILIZATION

Sterilization is done By Moist Heat Sterilization Method. Validity of sterilization applies as long as the sealed inner 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".

PATIENT IDENTITY CARD

The packaging contains product identification stickers 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.

DISPOSAL OF DEVICE

There is NO specific guideline for disposing of Non sterile or contaminated medical devices. Follow standard procedure for discarding outdated or contaminated products.

RETURN GOODS POLICY

AI OPTICS (P) LTD 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 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.

CUSTOMER FEEDBACK AND ADVERSE EVENTS REPORTING

Please report any feedback, adverse events/complaints to AI OPTICS (P) LTD., 84/1, Aavin Dairy Farm Road, SIDCO Industrial Estate, Ambattur, Chennai- 600098, INDIA. Email: info@appasamy.com.

HOW SUPPLIED

AI OPTICS (P) LTD, IOLs are supplied with Delivery system depends on customer requirement.

The Package Contains

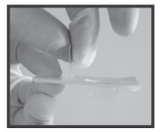
One Sterile Intra Ocular Lens, One sterile Lens Delivery system, Patient ID Card,Labels and Information for use (IFU).

AI OPTICS (P) LTD., recommends using the our IOL Delivery System 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(P)LTD., Lens Delivery system, please follow the "Instruction for Use of Delivery System."

NOTE: To avoid dehydration, leave lens see below 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 OPENING OF PRIMARY PACK

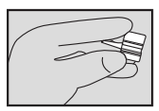


After opening the outer box, examine the device package for any damage, and verify that information (lens model, power, serial number, Expiry Date, etc.) Provided on the device primary pack is same as the information provided on the outer box label. Peel the Primary Pack and hold the PP cup in sealing free side by one hand. Slowly peel off the aluminium foil by other hand.

INSTRUCTION FOR USE OF AI OPTICS DELIVERY SYSTEM

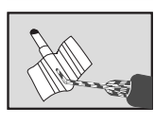
Sterilization of Delivery system is done By EO Sterilization Method.

STEP: 1



Open the cartridge using thumb and index finger. It is most convenient to load the lens.

STEP: 2



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. Please Refer "IOL loading Method" for place the lens into the chamber of the cartridge.

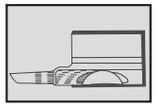
IOL LOADING METHOD

OPTIC DESIGN	HAPTIC DESIGN	METHOD
Bi-Convex (More than 7.0 D)& Concave-Convex (Less than 7.0 D)	Dual & C Haptic (601&502)	The lens should be placed into the cartridge barrel as Reverse "e". The anterior side of the lens should be like this 
Bi-Convex (More than 7.0 D)& Concave-Convex (Less than 7.0 D)	Plate Haptic (Ultrasmart)	This Lens has arrow mark in the right side of the top corner of Haptic. This arrow mark of the lens should be placed into anterior side of the Cartridge barrel.
Bi-Convex (More than 7.0 D)	Plate Haptic (701)	This lens can be placed in any side into cartridge barrel.
Concave-Convex (Less than 7.0 D)	Plate Haptic (701)	Concave side should be faced on the bottom of the cartridge (Posterior side).

STEP: 3

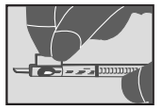
Use flat forceps to gently press the lens and at the same time, partially close the cartridge. Then gently push the leading and trailing haptic over the optic and close cartridge.

STEP: 4



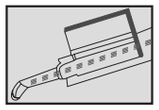
If it is unable to close the cartridge, and then open the cartridge, remove the lens and reload the lens following steps 2, 3 and 4. Make sure neither the haptic nor optic is caught between the shutters.

STEP: 5



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.

STEP: 6



Gently push the plunger until the lens moves towards the cartridge tip. The lens will completely come out of the cartridge.

SYMBOLS USED ON LABELING

D	Diopter (Spherical equivalent)
IOL	Intraocular lens
STERILE	Sterilized using Steam
	Do not Re-use the product
	Do not Re-sterilize the product
SN	Serial number
	Do not use if package is damaged
5°C 40°C	Store between 5°C to 40°C
	Consult Instructions for use
	Keep away from sunlight
	Keep dry
STERILE EO	Sterilized using Ethylene oxide
	Manufacturer
	Date of Manufacture
	Expiry Date
LOT	LOT Number
REF	Reference (Model) Number
ØB	Optic Diameter of IOL
ØT	Overall length of IOL
	Single sterile barrier system
	Double sterile barrier system
	Caution
CE ####	CE conformity Marking and the Notified body number
EC REP	Authorized Representative in the European Community/ European Union

EC REP **Amstermed B.V.**
Saturnusstraat 46-62, Unit 032,
2132 HB Hoofddorp, The Netherlands
Email: info@amstermed.nl

CE 2460

Manufacturing Licence No. MFG/MD/2025/000107
Manufactured by:

AI OPTICS PRIVATE LIMITED,
84/1, Aavin Dairy Farm Road,
SIDCO Industrial Estate, Ambattur,
Chennai – 600098, INDIA.

ACR-IFU-Ver 9.0 - 14 Feb 2025

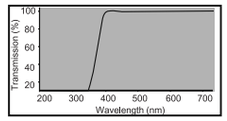
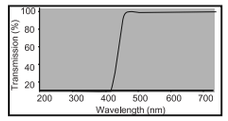
Acryfold®

FOLDABLE INTRAOCULAR LENS WITH DELIVERY SYSTEM

DESCRIPTION OF THE DEVICE

Intra Ocular Lenses are optical implants for the human crystalline lens in the visual correction of aphakia. The lens optic is lathe cut from HEMA blanks with UV blocking properties.

MATERIAL & PRODUCT CHARACTERISTICS

Material Characteristics					
Model	**601**	**502**	**701**	**Ultrasmart**	**601Y**
Color	Clear				Yellow
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	 Clear Material (601,502,701,Ultrasmart)				
	 Yellow Material (601Y)				

Product Characteristics		
Model	**601 & 601Y**	**502**
Optic Design	Bi-Convex / Convex- Concave	Bi-Convex / Convex- Concave
Haptic Design	Dual Haptic	C Loop
Drawing		
Optic Diameter	6.00 mm	6.00 mm
Overall Length	12.50 mm	12.50 mm
Power Range	-15.00 D to + 53.00 D (In steps of 0.5D)	-15.00 D to + 53.00 D (In steps of 0.5D)
Model	**701**	**Ultrasmart**
Optic Design	Bi-Convex / Convex- Concave	Bi-Convex / Convex- Concave
Haptic Design	Plate Haptic	Plate Haptic
Drawing		
Optic Diameter	6.00 mm	6.00 mm
Overall Length	11.00 mm	11.00 mm
Power Range	-15.00 D to + 53.00 D (In steps of 0.5D)	-15.00 D to + 53.00 D (In steps of 0.5D)

INTENDED USE AND MODE OF ACTION

Acryfold IOL 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. The following indications and contraindications are based on research of medical literature and are to be used only as guides. The list is indicative and not to be viewed as complete or comprehensive.

Throughout life, the crystalline lens protects the retina from hazardous UV light. Cataract extraction removes this protective barrier and may accelerate retinal photo toxicity to control the amount of radiation transmitted to the retina after cataract surgery. IOLs were created with the capability of blocking UV radiation. All IOLs today block short wavelength UV radiation upto 400nm.

Yellow IOLs approximate the UV and blue-light attenuating properties of the human crystalline lens. This IOL contains covalently bound chromophores, that providing increased protection against harmful UV light while allowing optimal blue light transmission, improving contrast sensitivity in low light conditions especially in eyes at risk of age-related macular degeneration.

Blue-absorbing chromophores added to IOL material to expand protection and decrease the amount of UV-blue energy Type as (400 nm to 500 nm range) reaching the retina. It is thought that adding a blue- blocking chromophores increased protection from photic retinopathy, because it simulated the properties of the natural crystalline lens.

INDICATIONS

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

CONTRAINDICATIONS

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list of specific contraindications must be respected: * Microphthalmia * Active ocular diseases (Chronic severe uveitis, Proliferative diabetic retinopathy, chronic glaucoma not responsive to medication) * Comeal de-compensation or endothelial insufficiency. * Comeal Opacification.

PRECAUTIONS

As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: Temporary Comeal Edema, Secondary Cataract Formation, Vitreous Herniation into the Formation, Mal-positionedLens, Aphakic Glaucoma, Temporary Flat Anterior Chamber, Retinal Detachment, Lens Implants Loop Amputation, Endothelial Corneal Dystrophy Anterior Chamber, Ocular Infection, Pupillary Block, Corneal Dystrophy and IOL opacification.

WARNINGS

1. Do Not Resterilize. Resterilization may compromaise device perfomance, 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 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 (P) Ltd., 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 (P) Ltd., makes no expressed or implied warranties in connection with sale of the IOL.