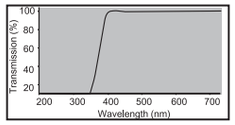
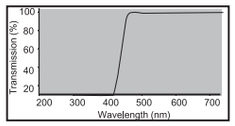
MULTIDIFF

FOLDABLE INTRAOCULAR LENS WITH DELIVERY SYSTEM

DESCRIPTION OF THE DEVICE

The MultiDiff 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. These lenses have two point supporting haptics for easy centration and aspherical surface on posterior side and Refractive-Diffractive surface on anterior side. The raw material characteristics of the lens are listed below

MATERIAL AND PRODUCT CHARACTERISTICS

Material Characteristics		
Model	**MFD605**	**MFDY605**
Material	Copolymer of Hydroxy Ethyl Methacrylate and Methyl methacrylate	
Colour	Clear	Yellow
Water Content	26%	
Refractive Index	1.46	
Minimum Resolution Efficiency	70%	
YAG Laser Compatible	Yes	
Light Transmittance	MFD605 	
	MFDY605 	

Product Characteristics		
Model	**MFD605**	**MFDY605**
Optic Design	Diffractive Refractive Optic	Diffractive Refractive Optic
Optic Type	Bi Convex/Convex-Concave	Bi Convex/Convex-Concave
Haptic Design	Dual Haptic	Dual Haptic
Drawing		
Optic Diameter	6.00mm	6.00mm
Overall Length	12.50 mm	12.50 mm
Power Range	0.00 D to +35.0 D (In steps of 0.5 D)	0.00 D to +35.0 D (In steps of 0.5 D)

INTENDED USE AND MODE OF ACTION

Foldable lens acts as refracting medium by replacing natural crystalline lens during aphakia correction. Multidiff IOL provides clear vision at both near and far. Indications and contraindications listed here are collected from approved medical literatures to be used only as guidelines.

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 up to 400nm.

Yellow IOLs approximate the UV and blue-light attenuating properties of the human crystalline lens. This IOL contains covalently bound chromophore, 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 chromophore added to IOL material to expand protection and decrease the amount of UV-blue energy (400 to 500-nm range) reaching the retina. It is thought that adding a blue- blocking Yellow chromophore increased protection from photic retinopathy, because it simulated the properties of the natural crystalline lens.

INDICATIONS

MultiDiff Posterior Chamber intra-ocular lenses are indicated for the replacement of human Crystalline lens to achieve visual correction of aphakia in the Cataract (Senile cataract, Traumatic cataract & Congenital cataract) patients. 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 Consider: • Microphthalmia • Active ocular diseases (Chronic severe uveitis, proliferative diabetic retinopathy, chronic glaucoma not responsive to medication) • Corneal de-compensation or endothelial insufficiency and Children under the age of 18 years • Corneal Opacification

PRECAUTIONS

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

WARNINGS

1. Do Not Resterilize. Resterilization may compromise 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 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.

STERILIZATION

The Lens is supplied in a Sterile Package. 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.

RETURNED GOODS POLICY

The returned lenses will only be accepted for exchange, not credit. A Returned Goods Number is obtained by contacting, Customer Service Department. Issuance of this number does not constitute final acceptance of the returned products. For detailed policy guidelines including exchange, please contact your Local Representative.

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 another Delivery system may cause damage to the lens and potential complications during the implantation process.

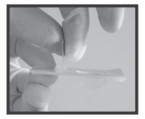
If using AI OPTICS (P) Ltd., Lens Delivery system, please follow the "Instruction for Use of Delivery System" (see below).

NOTE:

To avoid dehydration, leave lens 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.

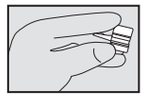


INSTRUCTION FOR USE OF DELIVERY SYSTEM

Sterilization of Delivery system is done By E0 Sterilization Method.

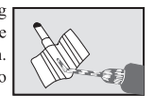
STEP: 1

Open the cartidge 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

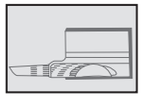
OPTIC DESIGN	HAPTIC DESIGN	METHOD
Bi-Convex (More than 7.0 D) & Convex- Concave (Less than 7.0 D)	Dual Haptic	The lens should be placed into the cartridge barrel as Reverse "S" The anterior side of the lens should be like this 

STEP: 3

Use flat forceepts 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

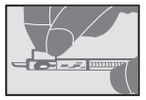
STEP: 4

If it is 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.



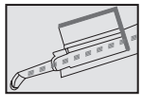
STEP: 5

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
PC	Posterior chamber
Adl	Additional power
A.Pwr	Actual power
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
	Keep away from sunlight
	Keep dry
STERILE EO	Sterilized using Ethylene oxide
	Consult Instructions for use
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:

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