PRODUCT INFORMATION

CM-T **Flex**

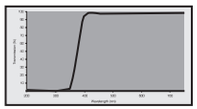
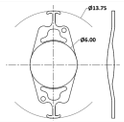
Scleral Fixation Hydrophilic

FOLDABLE INTRA OCULAR LENS

DESCRIPTION OF THE DEVICE

Intra Ocular Lenses are optical implants for the human crystalline lens in the visual correction of aphakia. CM-T-Flex Intra Ocular Lens is a single piece, sterile, foldable, hydrophilic acrylic optical device. The lens optic is lathe cut from HEMA blanks With UV blocking properties.

MATERIAL & PRODUCT CHARACTERISTICS

Material Characteristics	Product Characteristics
Colour: Clear	Optic Design : Bi-Convex / Convex -Concave
Material : Copolymer of Hydroxy Ethyl Methacrylate and Methyl Methacrylate	Haptic Design : T- Anchor Haptic on both sides
Water Content : 26%	Optic Diameter : 6.00mm
Refractive Index : 1.46	Overall Length : 13.75mm
YAG Laser Compatible : Yes	Power Range : -15 to +55D (0.5 D increments)
Material spectral Transmittance: 	IOL Picture: 
Method of Sterilization for IOL : Steam Sterilization	
Method of Sterilization for Disposable Injector System :EO Sterilization	

INTENDED USE

CM-T Flex intraocular lens is intended to be positioned in the sulcus in the bed of the sclera pocket and covered with a scleral mat by means of a special anchor with a self-locking system, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. It is suitable for aphakic eyes, without a capsular bag. Its anchoring to the scleral tissue using special anchors without the need for stitches, which simplifies surgery and greatly reduces its duration. It is not placed in the capsular bag. Instead, it is placed in the scleral who do not have an intact capsular bag or have a damaged capsular bag.

INDICATIONS

- Aphakia
- Microphthalmia
- Shallow anterior chamber (< 2.8 mm)
- Narrow angle, i.e. < Schaefer grade 2
- Congenital eye abnormality
- Pigment dispersion syndrome
- Pseudophakic patients with malpositioned, subluxated or unstable capsular fixated intraocular lens
- Inability to achieve secure placement in the designated location e.g. due to absence of a secure peripheral anterior capsule, absence of intact zonules, or irregular anatomy of the ciliary sulcus
- Active ocular diseases (chronic severe uveitis, proliferative diabetic retinopathy, chronic glaucoma not responsive to medication, iris atrophy, severe zonulopathy)
- Children and adolescents under the age of 18 years
- Corneal decompensation

CONTRAINDICATIONS

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list of specific contraindications must be respected:

- Corneal damage or edema
- Cystoid macular edema
- Secondary glaucoma
- Pupillary block
- Uveitis
- Iris trauma
- Intraocular infection
- IOL exchange or extraction
- Hemorrhage
- Postoperative opacification / calcification of the IOL
- Endophthalmitis
- Asthenopic discomfort, adaptional difficulties
- Reduced contrast sensitivity
- Reduced vision at night or in poor visibility conditions
- Perception of halos or radial lines around point sources of light
- Dissatisfactory visual outcome due to incorrect IOL refraction

PRECAUTIONS

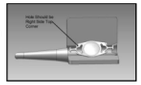
As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: Temporary Corneal Edema, Secondary Cataract Formation, Vitreous Herniation into the Formation, Mal-positioned Lens, Aphakic Glaucoma,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

WARNINGS

1. Do not Re-sterilize.
2. Lens should not be altered in any manner.
3. Lens should not be repackaged by anyone.
4. Single use IOLs and single use injectors cannot be reused to avoid microbial contamination, as they are not designed to perform as intended after the first and only usage.
5. Do not use after the expiry date.
6. IOLs should be handled carefully to avoid damage to the lens optics or haptics. Non- toothed, polished instruments should be used, without grasping the optical area with forceps.
7. Do not allow the IOL to contact substances that are unsterile or ocular-incompatible prior to placement into the eye.
8. Do not use unsterile surgical instruments or instruments that may carry a risk of contamination.
9. Do not allow the IOL to dehydrate during the procedure.
10. Do not implant the IOL into the capsular bag.
10. Once closed, do not reopen the flaps of the injector.
11. Following implantation, irrigate/aspirate to eliminate any viscoelastic residues from the eye, especially between the IOL and posterior capsule.
12. Patients with chronic autoimmune diseases under long term treatment should be considered as risk patients since exacerbation of their condition might occur.

Any damage to the peel-pouch or any accidental opening of the peel-pouch is to be declared as "NON STERILE".

IOL LOADING METHOD



This Lens has two Holes. The lens should be placed on the cartridge loading Chamber like one Hole is in the right side of the top (upper) corner and another one is left side bottom corner of the Haptic as shown in the picture.

PATIENT IDENTITY CARD

The packaging contains Patient ID Card for maintaining a record of the IOL implantation. Surgeons are requested to fill the required details and paste the product label and give the filled 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 / used medical devices. Follow local/national regulations and requirements for discarding outdated or contaminated products.

DISCLAIMER OF LIABILITY

AI Optics Private Ltd., accepts no liability for any Injury happened to patient as result of any improper implantation method or technique used by a physician to implant the lens. AI Optics Private Ltd., makes no expressed or implied warranties in connection with sale and use of the lens for any individual patient without prescription.

RETURN GOODS POLICY

AI Optics Private Ltd accepts returned lenses for exchanges only. No cash refunds will be issued. To return the lens, 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 their original invoice date.

CUSTOMER FEEDBACK AND ADVERSE EVENTS REPORTING

Please report any feedback, adverse events/complaints to AI Optics Private Ltd., 84/1, Aavin Dairy Farm Road, SIDCO Industrial Estate, Ambattur, Chennai-600098, INDIA.

Email: info@appasamy.com.

HOW SUPPLIED

AI OPTICS IOLs are supplied with Delivery system depends on customer requirement.

The Package Contains

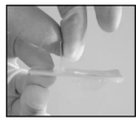
One Sterile Intra Ocular Lens, One sterile Lens Delivery system, Patient ID Card, Labels and Information for use (IFU).

AI Optics Private Ltd., recommends using 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 Private 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.

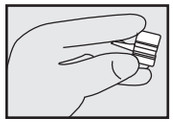
INSTRUCTION FOR OPENING OF PRIMARY PACK



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.

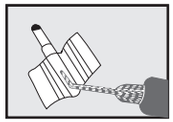
INSTRUCTION FOR USE OF AI OPTICS DELIVERY SYSTEM

STEP : 1



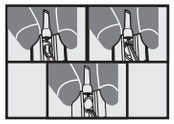
Open the cartridge using thumb and index finger. It is most convenient to load the Lens.

STEP : 2



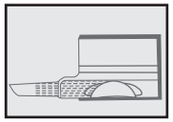
Apply a thin layer of viscoelastic in the lens loading chamber and in the barrel to serve as a lubricant for the free movement of lens through the cartridge during injection. Since the lens has square edge on its posterior side, place the lens in the loading chamber of the cartridge to ensure that posterior side of the lens face downwards.

STEP : 3



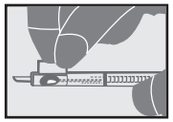
Use flat forceps to gently press the lens and at the same time, partially close the cartridge. Then gently push the haptics and optic to place properly inside the loading chamber and close the cartridge.

STEP : 4



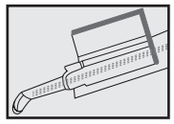
If it is not possible to lock the cartridge, then open the cartridge, remove the lens and reload the lens following steps 2, 3 and 4. Make sure neither the haptic nor optic is caught between the shutters.

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
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
	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

Manufacturing Licence No. MFG/MD/2025/000107

Mfgd by:

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