CM-T Flex

1 DEVICE IDENTIFICATION AND DESCRIPTION

Device Name: CM-T Flex (Model: Acryflex-T).

Description: Intra Ocular Lenses are optical for the human crystalline lens in the visual correction of aphakia. CM-T-Flex Intra Ocular Lenses is a single piece, sterile, foldable, hydrophilic acrylic optical device

Single-Use Only: Do not reuse or resterilize.

1.1 Supply and Packaging

HOW SUPPLIED AI Optics Private Limited IOLs are supplied with a delivery system depending on customer requirements.

The Package Contains:

- One (1) Sterile Intraocular Lens
- One (1) Sterile Lens Delivery System
- Patient ID Card and Traceability Labels
- Instructions for Use (IFU)

Delivery System Warning: AI Optics Private Limited recommends using the IOL Delivery System provided with our IOL for patient safety. The use of other delivery systems may cause damage to the lens and potential complications during the implantation process. If using the AI Optics Private Limited Lens Delivery System provided with our IOL, please follow the specific “Instructions for Use of Delivery System” detailed in Section 11.2.

2 INTENDED PURPOSE AND CLINICAL INFORMATION

2.1Intended Purpose

It 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 sulcus who do not have an intact capsular bag or have a damaged capsular bag.

2.2Indications

The device is indicated for secondary intraocular lens (IOL) implantation to restore emmetropia in adult patients requiring scleral fixation due to:

- Surgical or congenital aphakia.
- Dislocated or subluxated primary IOL.
- Inadequate capsular/zonular support post-complicated cataract surgery.
- Post-traumatic lens absence.

2.3 Contraindications

The CM-T Flex must not be implanted in eyes with:

- **Active Intraocular Infection:** Any sign of active or recent endophthalmitis.
- **Active Inflammation:** Uncontrolled uveitis or severe chronic internal ocular inflammation.

2.4 Target Population

- The device is primarily recommended for adults aged 18 years 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.

2.5 Intended User

The CM-T Flex IOL must be used exclusively by appropriately trained ophthalmic surgeons experienced in sutureless scleral-fixated IOL (SFIOL) techniques.

2.6 Summary of Safety and Clinical Performance (SSCP)

A summary of the safety and clinical performance of this device is available to the public via Eudamed at: **https://www.appasamy.com/ai-optics**

3 CLINICAL PERFORMANCE

The clinical performance of the **CM-T Flex Intraocular Lens** has been established through clinical evaluations and peer-reviewed publications, demonstrating its effectiveness in refractive rehabilitation and long-term stability for eyes without capsular support.

3.1 Clinical Benefits

The primary clinical benefits of the device include:

- **Restoration of emmetropia** in adult patients with surgical or congenital aphakia.
- **Stable sutureless trans-scleral anchoring** that eliminates the need for complex haptic manipulation, such as tucking or suturing.
- **Rapid visual rehabilitation** through a simplified "grasp, exteriorize, and release" surgical technique.

3.2 Performance Characteristics

- **Optical Performance:** The aspherical optic functions as a refractive medium to replace the natural crystalline lens. Clinical data show significant improvement in Best-Corrected Visual Acuity (BCVA) for both distance and near vision.
- **Mechanical Stability:** The 13.75mm overall length and unique T-shaped haptic design provide a self-stabilising mechanism that prevents rotation along the long axis and slippage into the vitreous cavity.
- **Physiological Positioning:** The 10° haptic vault ensures the lens remains clear of the iris, reducing the risks of pigment dispersion, pupillary block, and chronic inflammation.

3.3Summary of Clinical Evidence

Clinical studies confirm the device achieves its intended purpose with high reliability:

- **Visual Acuity Improvement**: In a 2-year long-term study (n=57 eyes), mean distance BCVA improved from 1.26 ± 0.84 logMAR at baseline to 0.51 ± 0.73 logMAR at 2 years ($p < 0.001$). Near BCVA improved from 1.28 ± 0.58 logMAR to 0.89 ± 0.40 logMAR over the same period.

- **Long-term Stability**: Longitudinal follow-up (mean 39.77 ± 8.44 months) reported no instances of IOL decentration, dislocation, or haptic exposure. Ultrasound biomicroscopy (UBM) at 6 months post-operatively confirmed the IOL remained well-centered and stable without tilt.

- **Surgical Efficiency:** The device design allows for a shorter learning curve for surgeons and reduced surgical time compared to traditional 3-piece SFIOL techniques.

3.4Clinical Safety Profile

Based on clinical study cohorts, the following performance-related safety outcomes were observed:

- **Transient Complications:** The most common post-operative events included transient corneal edema (resolving from 17.54% at 1 week to 1.75% at 2 years) and anterior chamber reaction.

- **Incidence of CME:** Cystoid macular edema was noted in 5.26% to 10.5% of cases, consistent with standard SFIOL surgical benchmarks, and was successfully managed with conservative treatment without impacting final visual outcomes.

- **Serious Complications:** No major vision-threatening events such as endophthalmitis or retinal detachment were reported in the published clinical series for this device.

4 SAFETY INFORMATION: CONTRAINDICATIONS, RISKS, AND SIDE EFFECTS:

Based on the technical documentation, clinical evaluation reports, and the generally acknowledged state of the art for scleral fixation, this section has been drafted

4.1Residual Risks

Residual risks are those hazards that cannot be entirely eliminated through device design or manufacturing controls and are primarily associated with the surgical procedure and the clinical complexity of the target patient population.

The following residual risks are associated with the implantation of the **CM-T Flex Intraocular Lens**:

- **Permanent Vision Loss:** A potential consequence of severe surgical complications or secondary infections.

- **Toxic Anterior Segment Syndrome (TASS) and Chronic Inflammation:** Risk of sterile inflammatory reactions despite proper handling and sterilization.

- **Optic Decentration or Tilt:** While the device is designed for stability, centration depends on the surgeon accurately marking the 180° meridian and creating symmetrical sclerotomies.

- **Damage to Ocular Structures:** Risk of posterior capsule (PC) rent or iris trauma during intraocular maneuvers, vitrectomy, or IOL exchange.

- **Wound Leakage and Structural Instability:** Potential for temporary wound-related complications or leakage at the sclerotomy or corneal incision sites

4.2 Potential Adverse Events (Undesirable Side-effects)

The clinical safety profile of the CM-T Flex SFIOL is established through a synthesis of data from early feasibility studies and long-term post-market clinical series. The device demonstrates a predictable safety profile consistent with the State of the Art (SOTA) for sutureless scleral-fixated lenses.

4.2.1 Transient Post-operative Adverse Events

Clinical studies reported several transient complications, predominantly occurring within the first week of surgery and resolving with standard medical management:

- **Corneal Edema (CE):** Reported in 17.54% of eyes at 1 week, typically resolving to 5.26% at 1 month and 1.75% at 2 years.
- **Anterior Segment Reaction:** Cells and flare were observed in 14.03% of cases at 1 week, reducing to 8.77% by 1 month.
- **Transient IOP Elevation:** Intraocular pressure >30 mmHg was noted in 3.5% of cases at 1 week and 1 month post-implantation.
- **Vitreous Haemorrhage (VH):** Occurred in 1.75% of cases (one eye) and resolved spontaneously without secondary intervention.

4.2.2 Longitudinal and Technique-Specific Risks

- **Cystoid Macular Edema (CME):** Observed at rates between 5.26% and 10.5%. This is consistent with standard SFIOL benchmarks and was successfully managed with topical steroids and NSAIDs without impacting final visual outcomes.
- **Haptic Handling Risks:** Clinical data identified a specific risk of haptic breakage during the exteriorisation process. While the high-tensile material is designed to prevent breakage, improper handling or non-polished instruments may compromise haptic integrity.
- **Persistent Corneal Edema:** A small percentage of patients (**1.75%**) may experience persistent edema requiring long-term monitoring at 2 years follow-up.

4.2.3 Comparison with Predicate Safety Profiles and General SFIOL Risks

When compared to predicate flanged fixation (Yamane) and sutured SFIOL techniques, the CM-T Flex demonstrates a lower incidence of stability-related complications:

- **IOL Stability: No cases** of IOL decentration, dislocation, or subluxation were reported across the reviewed clinical series.
- **Haptic Integrity: No haptic exposure, erosion, or fracture** events were observed during the follow-up periods (mean 39.77 months).
- **Suture Erosion: Not applicable.** As this is an entirely sutureless procedure, risks associated with suture degradation, knot exposure, or suture-wick endophthalmitis are eliminated.
- **Major Vision-Threatening Events:** Although recognized as risks in general SFIOL surgery, **zero instances** of endophthalmitis, retinal detachment, or chronic hypotony were recorded for this device in the published clinical studies.

4.2.4 Non-Applicable Adverse Events

Based on the device design and the clinical status of the target population, the following standard IOL complications are **not considered applicable** for the CM-T Flex:

- **Anterior/Posterior Capsule Opacification:** As the device is indicated for aphakic eyes lacking a capsular bag, complications related to the crystalline lens capsule (including the need for Nd:YAG capsulotomy) are not applicable.

4.2.5 General Ophthalmic Surgical Hazards

The hazards and complications associated with the implantation of the CM-T Flex are essentially the same as those inherent to routine cataract extraction and secondary IOL placement. These hazards include, but are not limited to:

- **Procedural Hazards:** Vitreous herniation, temporary flat anterior chamber, and malpositioned lens.
- **Secondary Pathologies:** Secondary glaucoma, ocular hypertension, and the potential for secondary cataract formation if residual lens remnants are present.
- **Physical Hazards:** Intraocular foreign body debris and the risk of "loop amputation" (haptic breakage) if improper surgical tools are utilized.
- **Pupillary Issues:** Pupillary block and pupillary capture of the IOL.

4.2.6 Information for Patients

The surgeon must brief the patient regarding the following safety information and expectations:

- **Immediate Post-operative Expectations:** Patients may experience temporary blurred vision in the initial weeks following surgery. This is typically due to mild internal inflammation (cells and flare) or temporary corneal swelling (edema), which occurred in **14–17%** of study cases and usually resolves with treatment.
- **Long-term and Rare Risks:** Although the procedure is highly stable, patients must be aware of rare potential risks, including:
  - **Macular swelling (CME):** Fluid at the back of the eye, which can occur in **5–10%** of cases but is manageable with medicated drops.
  - **Internal bleeding:** A rare risk of vitreous haemorrhage (reported in **1.75%** of cases) that typically clears on its own.
  - **Serious Complications:** While not observed in specific CM-T Flex trials, general risks of this surgery type include retinal detachment or increased eye pressure.
- **Requirement for Compliance:** The success of the implant depends on strict adherence to the post-operative medicated drop regimen and attendance at all scheduled follow-up examinations to monitor lens stability.
- **Emergency Indicators:** Patients are advised to contact their surgeon immediately if they experience a sudden change or loss of vision, increased redness, or new ocular pain.

5 WARNINGS AND PRECAUTIONS:

5.1 Warnings

- **User Qualification:** This device must only be implanted by ophthalmic surgeons with specific training and experience in sutureless scleral-fixated IOL (SFIOL) techniques.
- **Learning Curve:** Surgeons should be aware that SFIOL procedures involve a steep learning curve. Increased vigilance is required during initial cases to mitigate risks of haptic damage or malpositioning.
- **OVD Removal:** Complete removal of all viscoelastic material is mandatory to prevent transient postoperative intraocular pressure (IOP) elevation.
- **Refractive Accuracy:** Precise preoperative biometry and keratometry are critical. Surgeons should personalize their A-constants to account for specific instrumentation and techniques.
- Patients with Endothelial corneal dystrophy are at increased risk of corneal endothelial cell loss during cataract surgery and intraocular lens implantation, which may lead to postoperative corneal edema or corneal decompensation and reduced visual outcomes.

5.2 Relative Contraindications and Clinical Considerations

The following conditions may increase the risk of poor surgical outcomes or postoperative complications. Implantation should only be considered after these conditions have been adequately managed and the surgeon has performed a thorough benefit-risk assessment:

- **Corneal Pathology:** Pre-existing corneal damage, significant opacity, or edema.
- **Glaucoma:** Advanced or uncontrolled secondary glaucoma.
- **Posterior Segment Issues:** Severe retinal pathology, active intraocular hemorrhage, or pre-existing cystoid macular edema (CME).
- **Structural Risks:** Scleral thinning or scleritis, which may compromise the stability of the T-anchor haptics.
- **Anatomical Irregularities:** Microphthalmia or irregular anatomy that precludes stable scleral fixation.
- **Poor Visual Prognosis:** Cases where the potential for visual improvement is limited independent of lens implantation.

5.3 Pediatric Use

This device is indicated for patients ≥18 years of age. Safety and effectiveness in pediatric patients have not been established. Any implantation in children requires a rigorous risk-benefit analysis by a qualified ophthalmic surgeon.

Key Clinical Risks:

- **Progressive Myopic Shift:** Continued axial eye growth in pediatric patients may lead to unpredictable, increasing myopia.
- **Visual Axis Obscuration:** Higher incidence of posterior capsule opacification (PCO) requiring secondary intervention.

- **Developmental Impairment:** Complications may disrupt visual development, potentially leading to amblyopia and strabismus.

- **Limited Symptom Reporting:** Patients may be unable to communicate photic phenomena (e.g., glare, halos), delaying the diagnosis of lens-related issues.

Surgeon Responsibility: Surgeons must perform a comprehensive pre-operative assessment and obtain informed consent, explicitly stating that the device is not indicated for pediatric use and that long-term outcomes remain unpredictable.

5.4 Precautions

- **Handling:** Use only non-toothed, highly polished instruments. Toothed instruments may cause haptic breakage or optic scarring.

- **Hydration:** Do not allow the IOL to dehydrate. The lens must be folded and implanted within 3 minutes of removal from its saline solution.

- **Long-term Follow-up:** Periodic clinical evaluation of IOL centration and haptic stability is recommended as part of routine postoperative care for implantable devices

5.5Caution

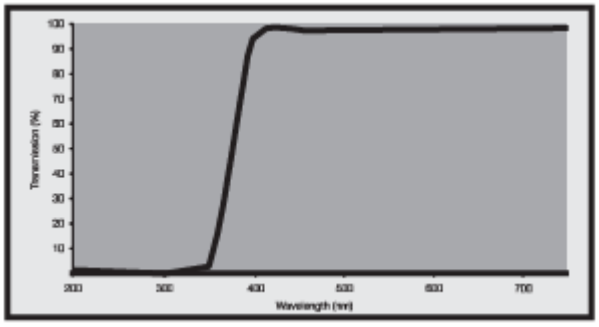
The CM-T Flex Intraocular Lens is intended for use exclusively by appropriately trained ophthalmic surgeons

6 PERFORMANCE AND TECHNICAL SPECIFICATIONS: (PREVIOUSLY SECTION 5—FOCUSED ON PHYSICAL/MATERIAL SPECS).

6.1Performance and Technical Specifications

The **CM-T Flex (Model: Acryflex-T)** is a single-piece, foldable intraocular lens designed with a unique T-anchor haptic system to ensure mechanical stability and predictable refractive outcomes when fixated to the sclera.

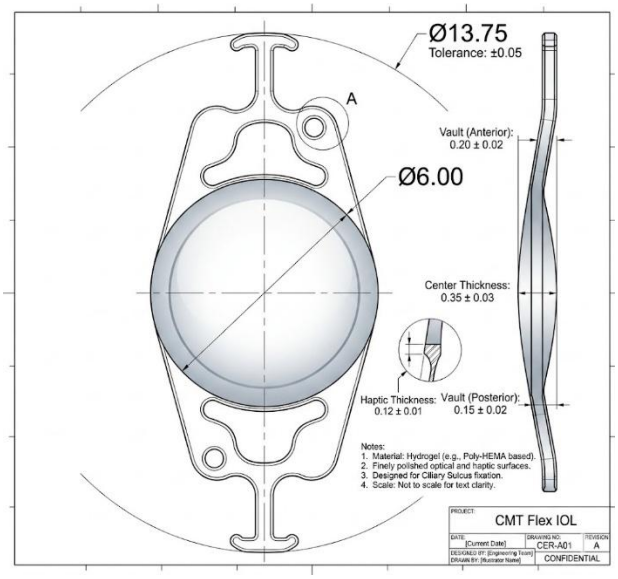
Physical and Material Specifications

Parameter	**Specification**
Model Name	Acryflex-T
Material	Hydrophilic Acrylic (Copolymer of HEMA and MMA)
Water Content	26%
Refractive Index	1.46 (at 35°C)
UV Transmittance	Integrated UV-blocking chromophores; <10% at 370nm 
Sterilization	Moist Heat (Steam) Sterilization

6.2 Optical and Mechanical Dimensions

The lens design utilizes a smooth transition from the optic to the haptic junction to reduce recesses that could engage the pupillary border.

- **Optic Diameter:** 6.00 mm.
- **Optic Design:** Bi-Convex or Convex-Concave aspheric configuration.
- **Overall Length:** 13.75 mm.
- **Haptic Design:** T-shaped anchor haptics on both sides.
- **Haptic Angulation (Vault):** 10° anteriorly vaulted to ensure physiological positioning and reduce iris contact.



6.3 Performance Characteristics

- **Refractive Performance:** Designed to restore emmetropia in aphakic eyes. Clinical data demonstrates a predictable refractive outcome, with median deviations from target typically within ≤ **±0.50 D**.
- **Mechanical Stability:** The T-shaped haptics provide a self-locking mechanism that eliminates the need for sutures, haptic tucking, or thermal flanging. Once exteriorised, the haptics hitch onto the scleral bed, preventing rotation along the long axis and slippage back into the vitreous cavity.
- **YAG Laser Compatibility:** The material is fully compatible with Nd:YAG laser procedures.
- **Biocompatibility:** The device is non-pyrogenic, non-cytotoxic, and non-genotoxic, meeting all requirements of the **ISO 10993** and **ISO 11979-5** standards.

6.4 Dioptric Power and A-Constant Guidelines

- **Dioptric Power Range:** Available from **-15.0 D to +55.0 D** in 0.5 D increments.
- **A-Constant (Theoretical):** 118.0.

- **Note on Calculation:** The A-constant provided is a guideline for initial power calculations. It is strongly recommended that surgeons **personalize their own A-constants** based on their specific surgical technique, measurement instrumentation, and preferred IOL power calculation formula (e.g., SRK/T).

6.5 Delivery System Compatibility

The lens is designed for implantation through a small clear corneal or sclero-corneal incision (approximately **2.8 mm**) using a compatible injector-based delivery system. The use of the manufacturer-provided sterile delivery system is recommended to ensure lens integrity during the folding and injection process.

7 IOL POWER CALCULATION AND A-CONSTANT

7.1 Calculation of Lens Power

- **Requirement for Accuracy:** Accurate preoperative Keratometry and Biometry are essential to ensure successful visual outcomes and patient satisfaction.
- **Surgeon Responsibility:** The required lens power for these posterior chamber intraocular lenses should be determined by the surgeon's clinical experience, professional preference, and the intended anatomic placement of the lens.
- **Recommended Formula:** Clinical studies for the CM-T Flex have successfully utilized the **SRK/T formula** for emmetropic targeting.

7.2 A-Constant Guidelines

- **Provisional Value:** The A-Constant listed on the device label and packaging is **118.0**.
- **Theoretical Basis:** This A-Constant has been **theoretically derived** and is not based on exhaustive clinical data. It is provided as a starting point and a guideline for initial implant power calculations.
- **Personalization of Constants:** It is strongly advised that the surgeon calculates their own personalized value for each style and specification of IOL to compensate for differences in instrumentation, measurement technique, and power calculation methods.
- **Initial Estimates:** A convenient initial estimate may be obtained by referencing the personalized lens constant for a similar lens model.

8 TRACEABILITY AND PATIENT INFORMATION.

8.1 Unique Device Identification (UDI)

The **CM-T Flex** is identified by a Unique Device Identifier (UDI) to ensure full traceability throughout the supply chain. The UDI consists of a **UDI-DI** (device identifier specific to the model) and a **UDI-PI** (production identifier relating to the lot or serial number). The Basic UDI-DI is referenced in the EU Declaration of Conformity.

8.2 Patient Identity and Implant Card

In accordance with **Article 18 of the MDR**, the manufacturer provides an **Implant Card** and identification labels with each device.

- **Identification:** The packaging contains product identification stickers to be pasted onto the patient's hospital record and the provided Patient ID Card.
- **Information for the Patient:** Surgeons must provide the completed Patient ID Card to the patient after surgery. This card allows the patient to identify the implanted device, including the model name, serial number, lot number, and manufacturer details.
- **Patient Briefing:** Patients should be advised to carry this card at all times to inform other healthcare providers of the implant in the event of future medical examinations or emergencies.

9 DISPOSAL AND INCIDENT REPORTING.

9.1 Reporting of Serious Incidents NOTICE:

Any serious incident that has occurred in relation to the CM-T Flex should be reported to **AI Optics Private Limited** and the **competent authority** of the Member State in which the user and/or patient is established.

- **Reporting Criteria:** Surgeons are requested to report any adverse reactions or potentially sight-threatening complications that are regarded as lens-related.
- **Timelines:**
  - Serious incidents must be reported immediately after a causal relationship is established, and no later than **15 days** after becoming aware of the event.
  - In the event of a serious public health threat, reporting must occur within **2 days**.

9.2 Disposal of the Device

The disposal of the intraocular lens must be conducted in a safe and effective manner in compliance with local health and safety requirements.

- **Contaminated Waste:** Explanted lenses or devices contaminated with potentially infectious substances of human origin (e.g., during a failed implantation) must be treated as **biohazardous waste**.
- **Physical Hazards:** Care should be taken when disposing of associated surgical delivery systems to avoid physical hazards from sharps.
- **Unused Devices:** Devices that are expired, damaged, or opened in an unsterile environment must be discarded according to institutional waste protocols.

10 MANUFACTURER AND ECONOMIC OPERATOR DETAILS.

10.1 Manufacturer Information

AI OPTICS PRIVATE LIMITED

84/1, Aavin Dairy Farm Road, SIDCO Industrial Estate, Ambattur, Chennai - 600098, INDIA. **Website:** www.appasamy.com

10.2 Authorized Representative in the EU (EC REP)

Saturnusstraat 46-62, Unit 032,
2132 HB Hoofddorp, The Netherlands.

Phone: +31 23 5656337
Email : info@amstermed.nl Website : www.amstermed.nl

10.3 Summary of Safety and Clinical Performance (SSCP)

The SSCP for the CM-T Flex is available to the public via the European database on medical devices (Eudamed) and can be accessed at the following link: **https://www.appasamy.com/ai-optics**.

10.4 External Identification

The device label contains symbols identifying the manufacturer, the date of manufacture, the expiry date, and the batch code to allow for precise identification by economic operators and competent authorities.

D	Diopter(Spherical equivalent)
IOL	Intraocular lens
STERILE	Sterilized using steam or dry heat
	Do not re-use
	Do not resterilize
SN	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
STERILE EO	Sterilized using Ethylene oxide
	Manufacture
	Date of Manufacture
	Expiry
LOT	LOT Number
REF	Reference (Model) Number
$Ø_B$	Optic Diameter
$Ø_T$	Overall Length
	Single sterile barrier system
	Double sterile barrier system
	Caution, Consult
MD	Medical Device
CE ####	CE conformity Marketing and the Notified body number

EC REP	Authorized Representative in the European Community/European Union

11 PREPARATION AND DIRECTIONS FOR USE

11.1 Preparatory Handling and Sterility Assurance

- **Sterility Inspection:** Prior to opening, the surgeon must carefully examine the peel-pouch to assure the sterile barrier is intact. Any damage to the peel-pouch must be viewed seriously; if the sterile seal is compromised, the IOL must be declared **"NOT STERILE"** and discarded immediately.

- **Opening Procedure:** After proper examination, peel the pouch and remove the internal Polypropylene (PP) Cup carefully. Hold the PP Cup and peel the aluminum seal to expose the lens.

- **Handling Precautions:**

  - **Contamination Avoidance:** Do not use rubber gloves dusted with **talc powder**, as this may cause severe intraocular irritation or inflammatory reactions.

  - **Solution Warning:** NEVER soak or rinse the IOL in any solutions (e.g., antibiotics or unrelated irrigation fluids) prior to implantation, as this may compromise the hydrophilic material.

  - **Hydration Maintenance:** The lens is supplied in its original saline solution to maintain its 26% water content. Leave the lens immersed in this saline until the surgeon is ready to fold and implant.

11.2 Pre-operative Preparation and Scleral Handling

- **Marking:** Use a Toric or dedicated marker to identify positions exactly **180° apart** (0° and 180° meridians). This step is critical to ensure the torsional stability and centration of the IOL.

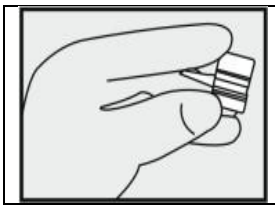
- **Peritomy:** Perform localized conjunctival peritomies at the marked sites.

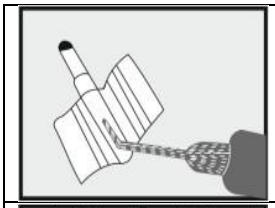
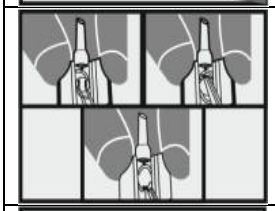
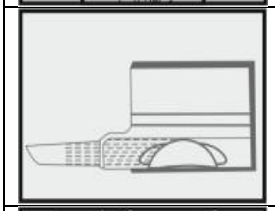
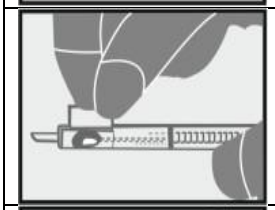
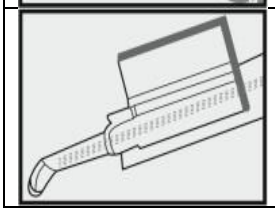
- **Scleral Flaps:** Create two partial-thickness, limbal-based scleral flaps (approximately 2.5 mm x 2.5 mm).

- **Sclerotomy:** Use a sharp **23-gauge needle** to create sclerotomies 1.5 mm from the limbus under each scleral flap

11.3 IOL Loading (Instruction for Use of Delivery System)

The delivery system steps from your original document should be detailed here:

	**Step 1:** Open the cartridge loading chamber.

	**Step 2:** Apply a thin layer of **viscoelastic** as a lubricant. Place the lens with the **posterior side (square edge) facing downwards**.
	**Step 3:** Use flat forceps to press the lens, push the leading and trailing haptics over the optic, and close the cartridge.
	**Step 4:** Ensure no haptic or optic parts are caught between the shutters before locking.
	**Step 5:** Load the cartridge into the injector groove.
	**Step 6:** Gently push the plunger until the lens is ready for deployment at the cartridge tip.

Crucial Hydration Note: To avoid dehydration, leave the lens immersed in its original saline solution until the surgeon is ready to fold and implant. The lens must be folded and implanted within 3 minutes after removal from the saline.

11.4 Surgical Implantation Technique

11.4.1 Leading Haptic Exteriorization:

- Introduce a 23-gauge PraNiv T Flex forceps into the vitreous cavity through one sclerotomy site.
- Inject the IOL through a 2.8 mm clear corneal incision.
- Grasp the leading haptic at the junction of the T-shaped arm.
- Perform the "PAP-Maneuver" (Pop After Pull): Gently pull the haptic through the sclerotomy until the T-shaped anchor "pops" out and hitches onto the scleral bed.

11.4.2 Trailing Haptic Exteriorization (Handshake Technique):

- While the trailing haptic remains at the corneal wound or on the iris, introduce a NiShi grasping forceps through a corneal side-port.
- Hold the arm of the IOL and use the handshake technique to transfer the trailing T-junction to the PraNiv forceps introduced through the second sclerotomy.
- Exteriorize the trailing haptic until it securely hitches onto the scleral bed.

- **Final Positioning:** Once both haptics are exteriorized, the IOL is self-centering and self-stabilizing. Verify centration before closing.

- **Closure:** Seal the scleral flaps and conjunctiva using fibrin glue to maintain an entirely sutureless procedure. Alternatively, fine sutures may be used to secure the flaps and conjunctiva according to surgeon preference, ensuring the exteriorised haptics are well-covered and protected from exposure

11.5 Post-Implantation

Eliminate all viscoelastic residues through irrigation/aspiration, particularly between the IOL and the posterior capsule

12 ADMINISTRATIVE AND COMMERCIAL INFORMATION

12.1 Return Goods Policy

- **Exchanges Only:** AI Optics Private Limited accepts returned lenses for exchanges only. No cash refunds will be issued.

- **Authorization Requirement:** To return lenses, you must obtain a Return Authorization **Number** from the Customer Services Department. No returned goods will be accepted without a proper authorization number.

- **Shipping:** Returned lenses should be shipped by a traceable method. No credit will be given for lenses lost or damaged in shipment.

- **Eligibility Period:** Lenses will be replaced provided they are returned within six months of the original invoice date.