**ENGLISH**

AST VisionCare, Inc. Version: Zo

TDRW-001001 Asqelio™ Mono and Toric_IFU_CE _Zo Date of Issue: 2026/05

CAUTION: Professional Use ONLY. The IFU should be provided to the patient with the Implant Card.

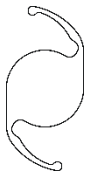
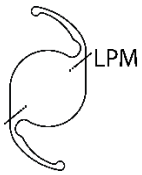
**Asqelio™ Monofocal Soft Hydrophobic Intraocular Lens QLIO130C, QLIO130Y**
**Asqelio™ Monofocal Toric Soft Hydrophobic Intraocular Lens TLIO130C, TLIO130Y**

## DEVICE DESCRIPTION

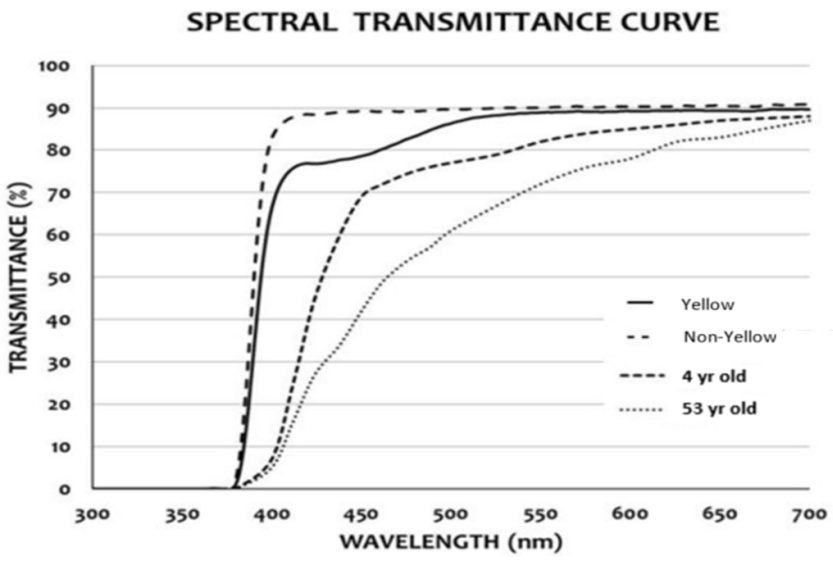
The Asqelio™ Monofocal Soft Hydrophobic Intraocular Lens (QLIO130 Series) and Asqelio™ Monofocal Toric Soft Hydrophobic Intraocular Lens (TLIO130 Series) are one-piece foldable posterior chamber, Clear (UV absorbing) or Yellow (UV + blue light absorbing), optical implant lenses used for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients. The Toric models also compensate for pre-existing corneal astigmatism and lead to the reduction of residual refractive cylinder.

The yellow IOL models (QLIO130Y, TLIO130Y) contain AST VisionCare's blue light filtering chromophore that filters light in a manner that approximates a young human crystalline lens in the 400-475 nm blue light wavelength range.

## LENS SPECIFICATIONS

| **Model** | **QLIO130Y** | **QLIO130C** | **TLIO130Y** | **TLIO130C** |
|---|---|---|---|---|
| Color | Yellow | Clear | Yellow | Clear |
| Material | The Asqelio™ IOL is polymerized from more than 98% acrylate materials to form the crosslinked hydrophobic acrylic copolymers covalently binding with a UV blocker and, for the yellow lens only, a blue light filtering chromophore (less than 1.5%).<br><br>The physicochemical studies reveal that no extractable substances arising from the manufacturing process or materials pose a safety risk. There is no toxicological safety concerns associated with the use of the device. | | | |
| UV Cutoff (10% T) | ≥ 384 nm | ≥ 382 nm | ≥ 384 nm | ≥ 382 nm |
| Exterior |  | |  | |
| Optic Design | Aspheric optic and one-piece design | | | |
| Material moisture content | < 0.5% | | | |
| Body Diameter | 6.0 mm | | | |
| Total Diameter | 13.0 mm | | | |
| A-constant (SRK/T) | Optical Biometry 119.3, Ultrasound Biometry 118.7 | | | |
| Sterilization method | Ethylene oxide (EtO) | | | |

| | |
|---|---|
| MRI Safety | The Asqelio™ IOL is magnetic resonance (MR) Safe. |




**NOTE:**

- Measurements are direct transmittance using a 6 mm aperture and a disc of thickness equivalent to the optic center of a 20.0 D lens.
- Human lens data from Boettner and Wolter, Transmission of the Ocular Media, Investigative Ophthalmology. 1962; 1:776-783.

**PERFORMANCE CHARACTERISTICS**

(1) Long term visual correction of aphakia in adult patients with or without presbyopia; and for Toric models only, a reduction of residual refractive astigmatism.
(2) Increased spectacle independence for distance vision.

**MODE OF ACTION**

The IOL is intended to be positioned in the posterior chamber of the eye, replacing the human crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. For Toric models, alignment of cylinder axis marks with the post-operative steep corneal meridian allows the lens to correct astigmatism.

**INTENDED PURPOSE AND INDICATIONS**

The QLIO130 Series and TLIO130 Series IOLs are indicated for the visual correction of aphakia and, for Toric models, reduction of residual refractive astigmatism, in adult patients with or without presbyopia in whom a cataractous lens has been removed, who desire improved uncorrected distance vision, reduction in residual refractive cylinder, and increased spectacle independence for distance vision. The devices are intended for capsular bag placement only.

**WARNINGS**

Physicians considering lens implantation should weigh the potential risk/benefit ratio for any circumstances that could increase complications or impact patient outcomes. This lens should not be implanted under the following conditions:

1. If the posterior capsule is ruptured, the zonules are damaged, or if a primary posterior capsulotomy is planned.
2. The Tyvek® pouch is found to be damaged or opened.
3. Suspected microbial infection.
4. Recurrent severe anterior or posterior segment inflammation or uveitis.

5. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment disease.
6. Surgical difficulties at the time of cataract extraction that might increase the potential for complications (e.g. persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
7. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
8. Circumstances that would result in damage to the endothelium during implantation.

**PRECAUTIONS**

1. Do not re-sterilize the lens by any method.
2. Do not store lens at a temperature outside the indicated range on the labeling.
3. Do not reuse the lens. The lens is for single use only. Re-use of the lens may cause re- or cross-infection leading to patient infection or explant of the lens.
4. Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS®) to rinse or soak lenses.
5. Handle lenses carefully to avoid damage to lens surface or haptics.
6. Do not attempt to reshape haptics in any way.
7. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant an intraocular lens.
8. Rotation of the lens away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, the lens repositioning should occur as early as possible prior to lens encapsulation. Some clinical cases suggest encapsulation is complete within four weeks of implantation. (Toric models only)
9. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. Residual viscoelastic may allow the lens to rotate causing misalignment with the intended axis of placement. (Toric models only)

**CONTRAINDICATIONS**

Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient's eyesight. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of the following conditions.

Before Surgery

1. Choroidal hemorrhage
2. Concomitant severe eye disease
3. Extremely shallow anterior chamber
4. Microphthalmos
5. Non-age-related cataract
6. Proliferative diabetic retinopathy (severe)
7. Severe corneal dystrophy
8. Severe optic nerve atrophy
9. Irregular corneal astigmatism
10. Medically uncontrolled glaucoma
11. Chronic severe uveitis
12. Diabetic retinopathy
13. Clinically significant macular/RPE changes
14. Color vision deficiencies

During Surgery

1. Excessive vitreous loss
2. Capsulotomy by any technique other than a circular tear
3. The presence of radial tears known or suspected at the time of surgery
4. A situation in which the integrity of the circular tear cannot be confirmed by direct visualization
5. Cataract extraction by techniques other than phacoemulsification or liquefaction
6. A situation where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
7. Posterior capsular rupture (preventing fixation of IOL)
8. Zonular damage (preventing fixation of IOL)
9. Uncontrollable positive pressure
10. Significant anterior chamber hyphema

**COMPLICATIONS**

The following lists potential complications accompanying cataract or implant surgery. Complications may include, but are not limited to the following:

Cumulative adverse events:

1. Corneal endothelial damage
2. Infection (Endophthalmitis)
3. Hyphema
4. Hypopyon
5. Lens dislocation
6. Cystoid macular edema
7. Corneal edema
8. Pupillary block
9. Cyclitic membrane
10. Iris prolapse
11. Retinal detachment
12. Vitritis
13. Transient or persistent glaucoma
14. Secondary surgical intervention (excluding retinal detachment and posterior capsulotomy), including but not limited to the following:
    a) Iridectomy for pupillary block
    b) Vitreous aspiration for pupillary block
    c) Repositioning of lens
    d) IOL removal due to inflammation
    e) IOL replacement
    f) Wound leak repair

Persistent Adverse Events:

1. Corneal Stroma edema
2. Cystoid Macular edema
3. Iritis
4. Raised IOP requiring treatment

Post-operative adverse events:

1.Lens rotation (Toric models only)
2.Visual distortion
3.Blurred vision at near distance

**SELECTION AND PLACEMENT OF TORIC MODELS**

The astigmatism to be corrected should be determined from keratometry and biometry data rather than refractive data since the presence of lenticular astigmatism in the crystalline lens to be removed may influence results.

The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. In order to optimize IOL selection and axis placement, AST VisionCare provides a web-based tool (www.astvc.com/toric-calculator*) for the surgeon. Preoperative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism are used to determine the appropriate spherical equivalent power, and axis of placement in the eye.

For optimal results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The anterior surface of the IOL is marked with indentations (three at each end) at the haptic/optic junction that identify the flat meridian of the optic. These indentations form an imaginary line representing the plus cylinder axis (note: IOL cylinder steep meridian is 90° away). The cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of placement).

Prior to surgery, the operative eye should be marked in the following manner: With the patient sitting upright, precisely mark the twelve o'clock and/or the six o'clock position with a T marker, a surgical skin marker, or a marking pencil indicated for ophthalmic use. Using these marks as reference points, an axis marker can be used immediately prior to or during surgery to mark the axis of lens placement following the use of the web-based tool (www.astvc.com/toric-calculator*) to determine the optimal axis of placement.

After the lens is inserted, precisely align the axis marking indentations on the IOL with the marked axis of lens placement. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. This may be accomplished by manipulating the IOL optic with the I/A tip and using standard irrigation/aspiration techniques to remove all viscoelastic from the eye.

Bimanual techniques may be used, if preferred, to ensure removal of viscoelastic from behind the lens implant. Special care should be taken to ensure proper positioning of the IOL at the intended axis following viscoelastic removal. Residual viscoelastic may allow the lens to rotate causing misalignment of the IOL with the intended axis of placement. Misalignment of the axis of the lens with the intended axis of placement may compromise its astigmatic correction.

Such misalignment can result from inaccurate keratometry or marking of the cornea, inaccurate placement of the IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the IOL after implantation.

In order to minimize this effect, the surgeon should be careful to ensure that preoperative keratometry and biometry is accurate and that the IOL is properly oriented prior to the end of surgery.

*toric calculator is verified and validated by an external party

**INSTRUCTIONS FOR USE**

1. Examine the label on the lens box for proper lens model, diopter power and expiration date.
2. Open the lens box to remove the pouched lens and verify the lens case information (e.g. power, model, serial numbers) is consistent with the information on the outer box.
3. This device is sterile until the inner pouch is opened. Inspect the pouch carefully for tears, cuts, punctures or other signs that the pouch has been opened or damaged. DO NOT implant the IOL if the sterility has been compromised.
4. To remove the lens, open the undamaged pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens.
5. To minimize the occurrence of marks on the lens due to handling, all instrumentation should be scrupulously clean. Any forceps used for lens handling must have round edges and smooth surfaces.
6. When removing the lens from the case, DO NOT grasp the optic area with forceps. The lens should be handled by the haptic portion only. Handle the lenses carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape haptics in any way.
7. Rinse the lens thoroughly using sterile intraocular irrigating solution such as BSS® or BSS PLUS® solution. DO NOT rinse the IOL in solutions other than sterile intraocular irrigating solution. Prior to insertion, the IOL should be carefully examined to ensure that particles have not adhered during handling.
8. AST VisionCare, Inc. recommends using BL-Cart™ IOL Delivery Cartridge (BL-Cart Series) bioli™ IOL Delivery System (BIOLI Series) or pioli™ IOL Delivery System (PIOLI Series) to insert QLIO130 Series and TLIO130 Series IOLs.
9. There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient. Surgeons should verify that appropriate instrumentation is

available prior to surgery.

10. DO NOT reuse this IOL. The device is for single use only. Re-use could result in device contamination or damage to IOL or cartridge.
11. DO NOT RESTERILIZE.

**HOW SUPPLIED**

The IOL is supplied dry, in a lens tray packaged in a Tyvek® peel pouch and terminally sterilized by ethylene oxide.

The lens must be opened only under aseptic conditions (See INSTRUCTIONS FOR USE above).

**STORAGE CONDITIONS AND EXPIRATION DATE**

Keep away from sunlight and keep dry. Do not store the product at a temperature outside the indicated range on the labeling. The packaged IOL is sterile unless the Tyvek® peel pouch is damaged or opened. The sterility expiration date is clearly indicated on the primary package and the outside box. DO NOT IMPLANT the IOL after the expiration date. Any lens held after the expiration date should be returned to the distributor.

**CLINICAL BENEFITS**

| Clinical benefit | Clinical outcome parameter |
|---|---|
| Improvements to vision, in persons previously afflicted with a cataractous lens | • Quantified measures in CVDA and UDVA post operatively in users of Asqelio Monofocal and equivalent devices, showing overall improvement in visual acuity, when compared to preoperative UVDA and CVDA<br>• A high level of satisfaction with vision, as reported by users of Asqelio Monofocal IOLs, during post-operative phase. |
| Greater spectacle independence as compared to pre-operative levels. | • Reported increase in spectacle independence in surveyed users of Asqelio Monofocal and equivalent devices.<br>• High level of post-operative patient reports of satisfactory visual acuity<br>• High post-operative level of long-term satisfaction reported by users of Asqelio Monofocal IOLs, during post-operative phase. (Based upon clinical data from PMCF and PMS activities) |

**EXPECTED LIFETIME**

The expected lifetime of the implant is set at 20 years.

**MEDICAL DEVICE DISPOSAL METHOD**

Method of disposal for this device should be carried out as infectious waste according to local regulations.

**REPORTING**

Serious incidents in relation to the device should be reported immediately to AST VisionCare, Inc. and the competent authority of the Member State where the event has occurred.

To report serious incidents, contact your local distributor or AST VisionCare directly via email at ra@astvc.com

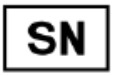
**SUMMARY OF SAFETY AND CLINICAL PERFORMANCE**

The SSCP is available in the European database on medical devices (Eudamed). Keyword search "AST VisionCare" at: https://ec.europa.eu/tools/eudamed

**5 STEP INSTRUCTIONS FOR COMPLETION OF THE IMPLANT CARD**

1. Name of the patient or patient ID. To be filled by the healthcare institution/provider.
2. Date of implantation. To be filled by the healthcare institution/provider.
3. Name and address of the healthcare institution. To be filled by the healthcare institution/provider.
4. R refers to IOL implanted in the patient's right eye; L refers to in the left eye.
5. Add the label on the dashed box.

**SYMBOLS USED ON IMPLANT CARD AND PACKAGING**

| SYMBOL | DESCRIPTION | SYMBOL | DESCRIPTION |
|---|---|---|---|
|  | Model Number |  | Patient ID |
|  | Medical Device Name |  | Implant Date |
|  | Serial Number |  | Name and address of the healthcare institution |
|  | Batch Code |  | Patient Information Website |
|  | Unique Device Identifier |  | Right Eye |
|  | Authorized Representative in the European Community |  | Left Eye |
|  | Authorized Representative in Switzerland |  | Total Diameter |
|  | Sterilized Using Ethylene Oxide |  | Body Diameter |
|  | Single Sterile Barrier System |  | Do Not Use If Package Is Damaged |
|  | Manufacturer |  | Do Not Re-use |
|  | Date of Manufacture (YYYY-MM-DD) |  | Do Not Resterilize |
|  | CE Marking |  | Importer |
|  | Consult Instructions for Use |  | Use-by Date (YYYY-MM-DD) |
|  | Temperature Limit |  | Keep Dry |
|  | Keep Away from Sunlight | | |

*Asqelio™, BL-Cart™, pioli™ and bioli™ are trademarks owned by AST VisionCare, Inc.
**Tyvek® is a registered trademark of E.I. DuPont de Nemours and Company
*** BSS® sterile irrigating solution is a registered trademark of Alcon Laboratories, Inc.

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