ENGLISH

AST VisionCare, Inc. Version: Z0

TDRW-001004 Asqelio PL Mono and PL Toric_DFU_CE_Z0 Date of Issue: 2026/05

CAUTION: Professional Use ONLY.

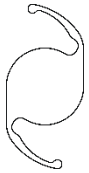
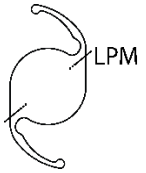
Asqelio™ Monofocal Preloaded IOL Delivery System **QPIO130C, QPIO130Y**
Sterile Asqelio™ Monofocal Soft Hydrophobic Acrylic Intraocular Lens with a Sterile Single-use Injector
Asqelio™ Monofocal Toric Preloaded IOL Delivery System **TPIO130C, TPIO130Y**
Sterile Asqelio™ Monofocal Toric Soft Hydrophobic Acrylic Intraocular Lens with a Sterile Single-use Injector

DEVICE DESCRIPTION

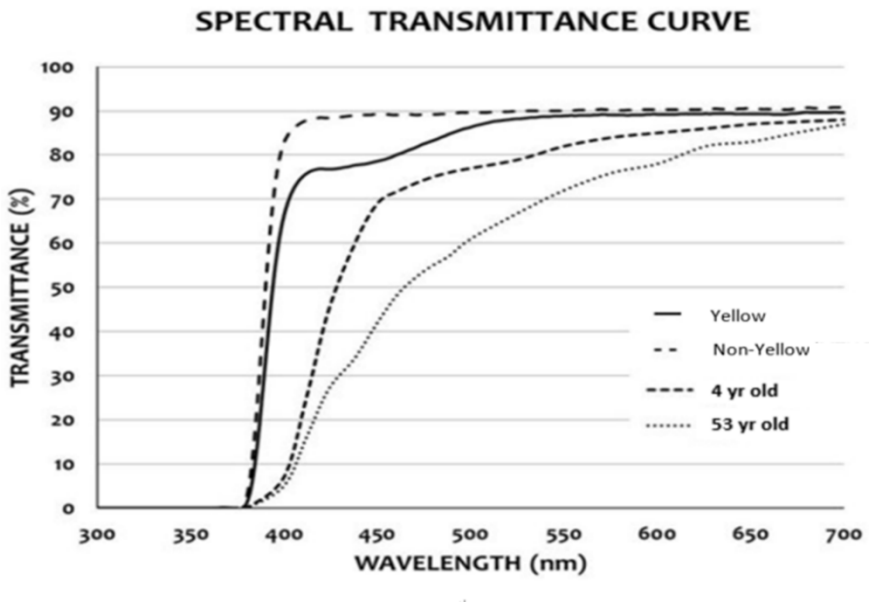
Asqelio™ Monofocal Preloaded IOL Delivery System (QPIO130 Series) and Asqelio™ Monofocal Toric Preloaded IOL Delivery System (TPIO130 Series) consist of a single-use injector containing a preloaded one-piece foldable posterior chamber UV- absorbing optical implant lens used for the replacement of the 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 preloaded system allows for insertion of the lens into patient's eye through a small incision.
The yellow IOL models of preloaded systems (QPIO130Y, TPIO130Y) 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	**QPIO130Y**	**QPIO130C**	**TPIO130Y**	**TPIO130C**
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%). 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™ Preloaded IOL Delivery System 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 Asqelio™ Preloaded IOL Delivery System comes fully assembled and preloaded with a one-piece IOL thereby eliminating the need for the end user to manually load the IOL into the lens delivery system. The IOL in the Asqelio™ Preloaded IOL Delivery System 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.

INTENDED PURPOSE AND INDICATIONS

The IOLs in the QPIO130 Series and TPIO130 Series preloaded systems 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. 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. Suspected microbial infection.
3. Recurrent severe anterior or posterior segment inflammation or uveitis.
4. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment disease.
5. 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).
6. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
7. Circumstances that would result in damage to the endothelium during implantation.

PRECAUTIONS

1. Do not use if the Tyvek® lid of the blister is found to be damaged or opened. The Tyvek® blister packaging must be opened only under aseptic conditions (See Instructions for Use below).
2. This is a single-use ethylene oxide-sterilized device. Do not re-sterilize the lens by any method.
3. Do not store lens at a temperature outside the indicated range on the labeling.
4. Do not reuse the lens. The lens is for single use only. Re-use of the lens may result in device contamination, cause re- or cross-infection leading to patient infection or explant of the lens, or damage to IOL or cartridge.
5. Do not attempt to reshape haptics in any way.
6. 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.
7. Sodium hyaluronate-based viscoelastic solution, BSS® or BSS PLUS®, is recommended to be used with Asqelio™ Preloaded IOL Delivery Systems.
8. Adjust the lens with a sterile tool only if needed and handle carefully to avoid damage to the lens surface or haptics.
9. Folding and compression of the lens should be done prior to insertion and delivery. Failure to follow the instructions for use may result in patient injury.
10. 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)
11. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. Residual viscoelastic may allow the lens to rotate causing misalignment of the lens 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 made 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. 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. Situation in which 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), include, 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 are accurate, and that the IOL is properly oriented prior to the end of surgery.

* The toric calculator is verified and validated by an external party

INSTRUCTIONS FOR USE

1. Examine the label on the sealed outer box for model, lens power, expiration date, and serial number.
2. Remove the device from outer box, inspect the sterile package for any damage and confirm its integrity.
3. Verify that the information on the sterile package label (e.g., model, lens power, expiration date, and serial number) is consistent with that on the outer box label.
4. While in sterile environment, peel back the Tyvek® lid and remove Asqelio™ Preloaded IOL Delivery System from the sterile blister packaging.
5. Inspect the position of the orange tip cushion. The tip cushion should be clearly visible and positioned within the cartridge chamber as shown in **Figure 1.**
6. Inspect the position of the trailing haptic of the IOL. The trailing haptic should be aligned with the back edge of the cartridge and the tip cushion on the plunger should not be in contact with the trailing haptic **(Figure 2)**.

   If the IOL or its haptic deviates from the correct position **(Figure 3)**, use appropriate sterile tools to adjust the lens or haptic before Step 7.
7. Fully insert the viscoelastic cannula into the top insertion port **(Figure 4)**. Inject about 0.1-0.2 mL of appropriate viscoelastic until it is observed slightly flowing backwards into the cartridge chamber.
8. Pull back on the orange housing to secure the cartridge. The cartridge is fully closed by now **(Figure 5).**
9. After closing the housing, slightly advance the plunger forward and the tip cushion will subsequently

push the IOL toward the nozzle end. The IOL is now ready for insertion through the incision.

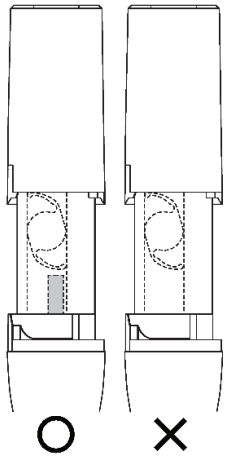


Figure 1

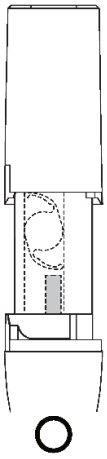


Figure 2

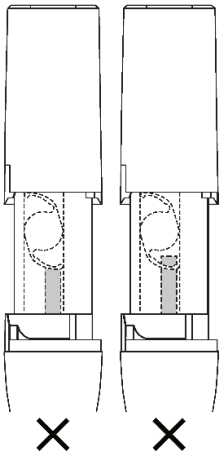


Figure 3

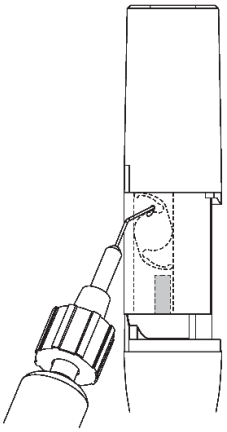


Figure 4

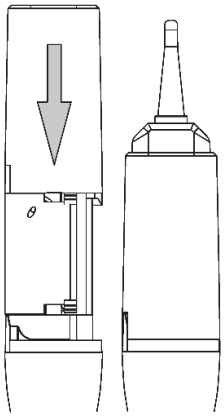


Figure 5

SURGICAL CAUTION

1. Prior to implantation, no parts of the IOL should be allowed to exit the loading chamber end. The lens should be injected immediately after being introduced into the cartridge as viscoelastic solution may lose its lubricating properties when exposed to air for a long period of time.
2. The appropriate surgical procedures are the responsibility of the individual surgeon. The surgeon must assess the appropriateness of the relevant procedure based on his/her medical training and expertise.
3. Deep placement of injector tip into the eye may lead to damage to capsular bag.

WARRANTY AND LIMITATION OF LIABILITY

The manufacturer warrants that reasonable care was used in making of this product. The manufacturer shall not be responsible for any immediate, subsequent or consequential loss, damage, or expense, which arises directly or indirectly from the use of this product. The manufacturer's liability shall be limited to the repair or replacement of any products found to be defective other than a result of improper handling.

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® packaging 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 • 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. • High level of post-operative patient reports of satisfactory visual acuity • 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.

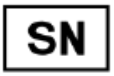
REPORTING
Serious incidents in relation to the device should be reported immediately to AST VisionCare, Inc. and the competent authority of the Member State where the event has occurred.

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 ID 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 Electronic Instructions for Use		Use-by Date (YYYY-MM-DD)
	Temperature Limit		Keep Dry
	Keep Away from Sunlight		

*Asqelio™ is a trademark 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.

AST VisionCare, Inc.
9 Linnell Circle, Billerica, MA 01821, U.S.A.

EC REP

MDSS GmbH
Schiffgraben 41, 30175 Hannover, Germany

CH REP

MDSS CH GmbH
Laurenzenvorstadt 61, 5000 Aarau, Switzerland

www.astvc.com/eifu

www.astvc.com

CE 2797