

## Instructions For Use

### 1stQ Basis IOL - Preloaded

#### Hydrophobic preloaded intraocular lens for implantation into the capsular bag

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#### Content:

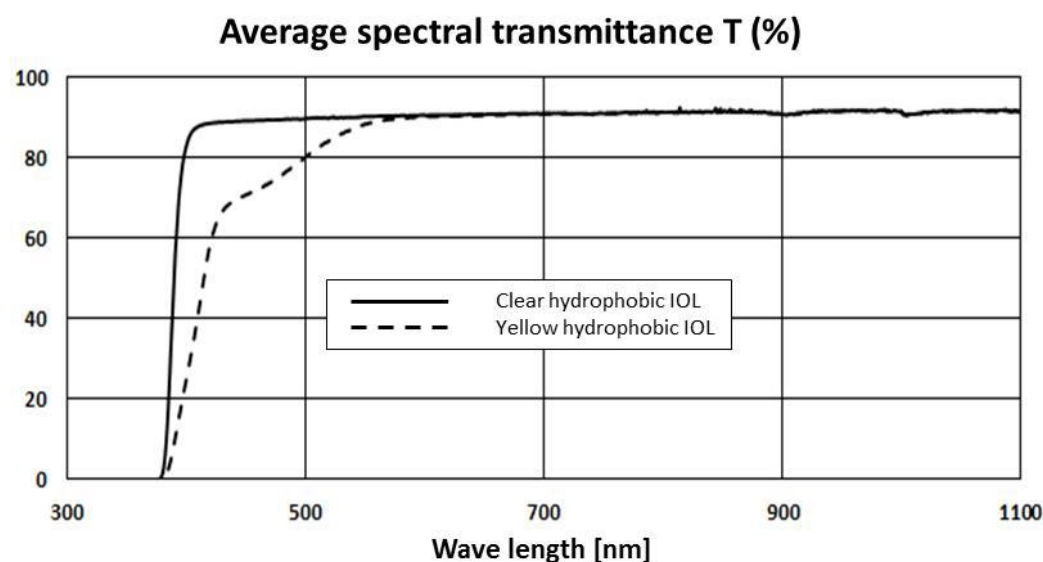
A one-piece sterile preloaded foldable aspherical intraocular lens (IOL) with sharp edges for single use consisting of highly purified hydrophobic acrylate with covalently bonded UV absorber. Some of the acrylic lenses are manufactured optionally with covalently bonded yellow chromophore as blue light filter. This is marked with Y in the product code.

#### Description:

This intraocular lens is an optical product of the highest precision. The manufacturing and the quality management system of 1stQ is in accordance with international standards and is certified according to ISO 13485 and 93/42/EEC.

1stQ preloaded hydrophobic intraocular lenses and their appropriate injection device are pre-assembled and packaged in one box. The parts of the injector are: injector body, adapter, rotatable ring, cartridge, stopper, plunger with a soft tip, spring.

The optical properties of the lens, e.g. refraction power as well as the dimensions (size of optics, total size of IOL) are indicated on the labels on the primary and secondary packaging.



The sharp edge design of this IOL creates an effective barrier against posterior capsule opacification (PCO) and reduces the rate of PCO development. However it cannot be excluded, that some patients may experience clinically significant PCO after surgery.

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### **Packaging:**

The preloaded hydrophobic IOL is packed into the injector and the entire system is packaged in a dry sterile blister.

The overall packaging contains the product, a set of stickers for administrative purposes identifying the product and a patient card to be completed and given to the patient.

### **Transportation, Storage and Waste Management:**

Handle with care.

Store at room temperature.

Do not expose to direct sunlight or extreme temperatures.

Do not freeze.

Keep dry, protect from moisture / water.

The product or its waste material should be disposed in accordance with local/national regulations and requirements.

### **Sterilization and expiration:**

Hydrophobic preloaded IOLs (including injector) have been sterilized by ethylene oxide, after being packed under clean room conditions.

Sterility is guaranteed only when the packaging is neither opened nor damaged. The applied sterilisation procedure and the expiration date are marked on the labels on the primary and secondary packaging. Do not use the IOL after its expiry date.

### **Indications of use:**

Implantation into the capsular bag in the posterior chamber of the adult eye after surgical removal of a cataractous lens to replace the human natural crystalline lens. This IOL can correct a previous refraction error.

### **Contraindications:**

There are no known contraindications to the implantation of a monofocal intraocular lens into the capsular bag.

### **Precautions:**

Careful preoperative evaluation and clinical judgment should be made by the surgeon prior to surgery to decide the benefit/risk ratio of the implantation in the following pre-existing conditions as described in the relevant medical literature:

- choroidal hemorrhage, bleeding disorders
- anatomical variances e.g. difficult access to eye (e.g. deep set eyes), microphthalmos, extremely shallow anterior chamber, small myotic pupil
- severe corneal dystrophy
- zonular laxity or dehiscence/separation and potential phacodonesis and lens subluxation
- uncontrolled glaucoma
- diabetes including its complications, e.g. (proliferative) diabetic retinopathy
- retinopathy of prematurity in the medical history

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- recurrent anterior or posterior segment inflammation of unknown aetiology
- significant vitreous loss
- posterior capsular rupture
- severe optic nerve atrophy
- colour vision deficiencies
- chronic uveitis
- clinically significant macular/RPE changes
- retinal detachment
- monocular patient
- current or recent treatment with any anticoagulant or antiplatelet medication or systemic alpha-1a adrenergic antagonists (e.g. tamsulosin)
- prior ophthalmic surgery e.g. keratorefractive surgery, penetrating keratoplasty, pars plana vitrectomy, scleral buckling surgery
- any concomitant severe eye disease including uveitis, glaucoma, high hyperopia and myopia, pseudo-exfoliation syndrome
- corneal diseases, like Fuch's corneal endothelial dystrophy, severe corneal dystrophy, irregular corneal astigmatism
- iris disorders, like synechiae, essential iris atrophy, rubeosis iridis
- special cataract types, e.g. hard/dense (brown/brunescent) nuclear cataract, posterior polar cataract, white (mature cortical) cataract, cataract due to rubeola, non-age related cataract

### **Possible complications:**

As with any surgical procedure, there is risk involved.

The most common potential complications and undesirable effects accompanying cataract or implant surgery – some of them may lead to a secondary surgical intervention (e.g. IOL replacement or extraction) or medication – may include, but are not limited to the following

- damage to cornea, Descemet membrane or endothelia
- flat anterior chamber after lens extraction
- corneal (stromal) oedema, bullous keratopathy
- haemorrhage, hyphemia
- raised intraocular pressure, secondary glaucoma
- cystoid macular oedema
- uveitis
- iris trauma, pupillary block, iris prolapse, seclusio pupillae, iris capture, iritis, epithelial ingrowth
- intraocular infections, inflammation, endophthalmitis
- dissatisfactory visual outcome (e.g. due to incorrect IOL refraction), visual impairment, glares/blinding, secondary surgical or medicinal intervention
- retinal detachment
- hypopyon
- IOL dislocation, decentration, tilt, axial shift or, rotation of the IOL
- unanticipated surgically induced change in the cornea, e.g. astigmatism
- vitreous loss
- cyclitic membrane
- fibrotic reaction
- synechia
- wound gape, wound leak/dehiscence

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- thermal burns
- incorrect positioning of the IOL during surgery
- damage to the IOL during implantation
- damage to anterior and posterior capsule (e.g. ruptures, tears) or to the zonules
- capsular phimosis and capsule block syndrome
- posterior capsule opacification (PCO)
- postoperative opacification/calcification of the IOL, deposits, discoloration, decolouration
- asthenopic discomfort, adaption difficulties

### **Interactions:**

No direct interactions of the implanted IOL with drugs are known.

However, the current or previous treatment with systemic alpha-1a adrenergic antagonist (tamsulosin) may increase the perioperative complications of the cataract surgery. The use of antiplatelet and anticoagulant medications may increase the risk of haemorrhagic anaesthetic or perioperative complications.

The deterioration of the transparency of the IOL implanted into the human eye has been observed after the intraocular administration of SF6 or C3F8 gases. Visually significant haze may develop, that may lead to IOL exchange.

In reasonably foreseeable environmental conditions, no significant interaction or possible damage caused by exposition to magnetic fields, external electrical influences, electrostatic discharge, pressure or variation in pressure, thermal ignition sources and acceleration is known.

### **Warnings:**

- Keep these Instructions for use and read it carefully before you apply this medical device.
- The surgeon performing the implantation must inform the patient about the implant and all known side-effects and risks.
- The patient should be instructed to inform the doctor in charge properly about any side-effects after implantation.
- Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or may necessitate additional surgical intervention.
- Do not use if the sterilized package is moist, open or damaged.
- Do not re-sterilize by any means.
- Do not use if expired.
- Do not re-use. Any occasional re-use must be avoided as it may pose serious health risk either by non-sterility or by any mechanical defect caused by the previous use.
- Use only sterile intraocular rinsing solutions such as sterile Ringer's solution or sterile BSS solution.
- A temporary opaqueness of the lens may occur due to a considerable change of temperature (e.g. when stored below room temperature). This phenomenon does not damage the lens material and the lens reverts to transparency after equilibration.

### **IOL power calculation:**

Accurate up-to-date and complete keratometry, biometry, visual acuity data as well as an exact calculation of the needed refraction using the formulas available in the literature are inevitable for optimal visual results. It is essential that the measurements are carried out in a consistent manner

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using standardized settings. Calculation may need the contribution of properly qualified optometrists.

The label of a 1stQ IOL contains the relevant optical parameters of the lens. The A-constant value specified on the outer label is presented as a guideline. It is advised that surgeons personalize the constants they use based on their surgical techniques, equipment and postoperative results. If available, use an optimized IOL constant:

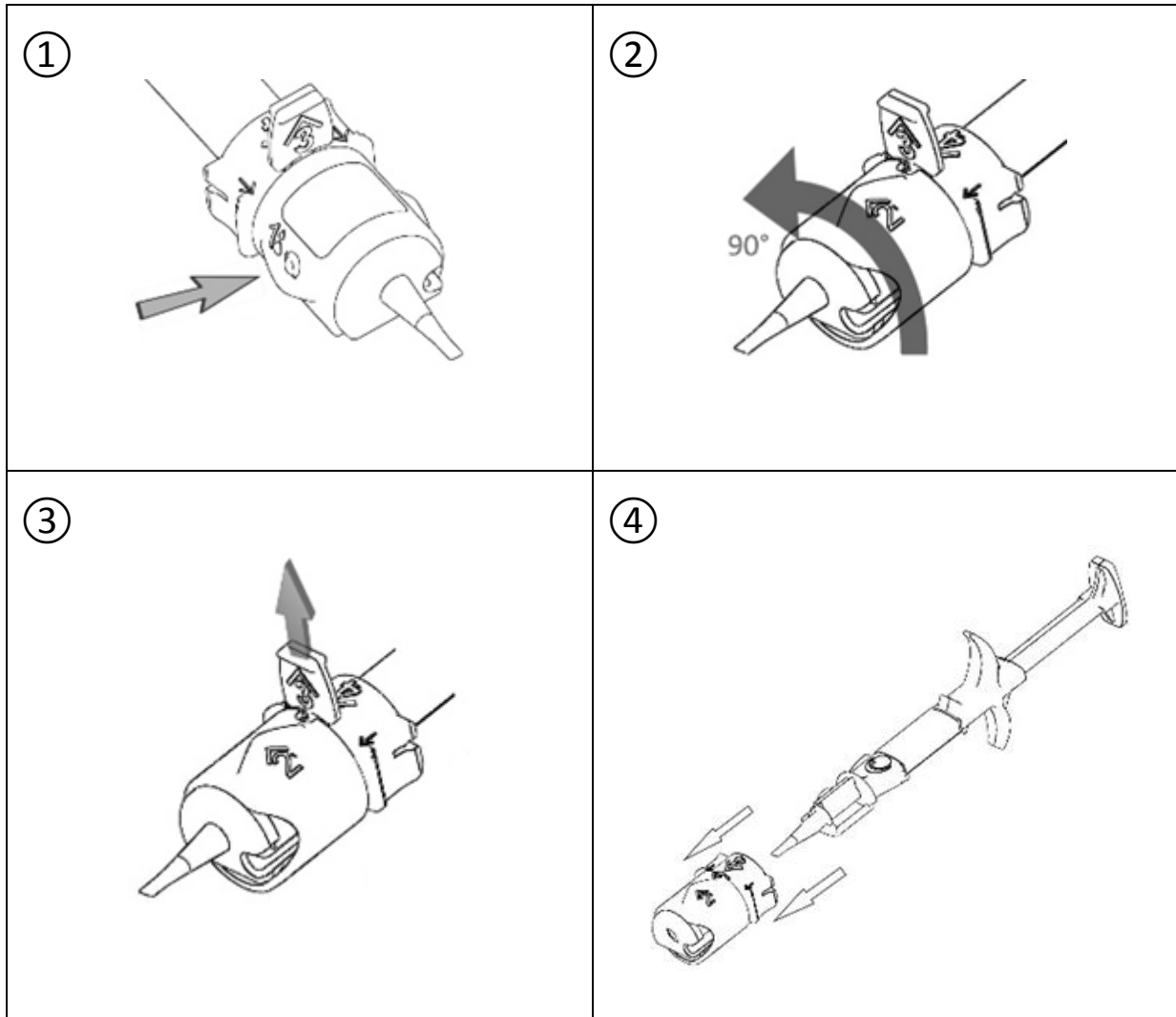
[www.augenklinik.uni-wuerzburg.de/ulib/index.htm](http://www.augenklinik.uni-wuerzburg.de/ulib/index.htm)

### **Handling:**

High level of surgical skill is required for proper implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more appropriate courses before attempting to perform implantation. Before performing the implantation the surgeon must read these instructions for use.

- It is recommended to store the lens the day before implantation at room temperature.
- Examine the package labels carefully for information about the lens model, power and expiration date
- Ensure that the IOL model and power corresponds with the results of the preoperative biometry.
- Open the outer package to remove the protective peel-pouch or blister and verify that the information is consistent with the outer package labelling (power, model and serial number).
- In a sterile environment open the protective peel-pouch or blister and remove the preloaded injector system.
- See Figure 1: Fully introduce the cannula (23G) of a syringe filled with viscoelastic material into the small aperture indicated with '1', maintaining a slight pressure on the cannula tip. Inject the dispersive viscoelastic solution (preferably HPMC) through the aperture. The injected quantity of visco is sufficient as soon as the two flows (drops) of the viscoelastic solution meet on top of the lens and become confluent. Balanced Salt Solution alone should not be used as lubricant.
- See Figure 2: Turn the transparent rotatable ring as indicated by the flat arrow marked with '2' counter-clockwise by 90 degrees until it snaps into place with a distinct "click".
- See Figure 3: Remove the red stopper indicated with '3' by pulling and discard it.
- See Figure 4: Remove the adapter together with the rotatable ring as indicated by '4' by pulling it off and discard it.
- With the nozzle tip bevel facing down, inject the IOL in a controlled manner. Do not use too much pressure. Anticipate a slight initial resistance. Excessive resistance could indicate a trapped lens. If the injector is blocked by the IOL, discard it.
- The entire injection should be one continuous process without interruption. Never pull the plunger back; otherwise the haptics might become damaged.
- When the lens exits the cartridge nozzle, stop pressing the plunger and carefully withdraw the cartridge nozzle tip from the eye.
- The surgeon must achieve perfect placement, orientation and centration in the capsular bag and emmetropia, for optimal results.
- Discard the injector after use.

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**Patient card:**

The relevant details should be entered onto the patient card enclosed. One of the stickers with the IOL details from the label set enclosed should be affixed on the back of the patient card. This card is to be given to the patient, who should take care of it so as to present it to any eye specialist in the future.

**References:**

- Holladay JT: Standardizing constants for ultrasonic biometry, keratometry and intraocular lens power calculations JCRS 1997, 23, 1356-70
- Cataract Surgery Guidelines - The Royal College of Ophthalmologists, September 2010
- Güell JL et al: Phakic intraocular lenses Part.1-2. JCRS 2010, 36, 1976-93 and 2168-94
- Retzlaff J., Sanders D. & Kraff M. Lens Implant Power Calculation. A Manual for Ophthalmologists & Biometrists. Third Edition, 1990
- Holladay J. A Three-part System for Refining Intraocular Lens Power Calculations. J. Cataract Refract. Surg. V14: 17-24. 1988

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Hoffer K. The Hoffer Q Formula: A Comparison of Theoretic and Regression Formulas. J. Cataract Refract. Surg. V19: 700-712. 1993

Holladay J.T., Gills J.P., Leidlen J, Cherchio M. Achieving emmetropia in extremely short eyes with two piggyback posterior chamber intraocular lenses. Ophthalmology 1996, 103: 1118-1123












G.L. van der Heijde: Optical Consequences of Implanting of a Concave Intraocular Lens Correcting Myopia, Klin. Mbl. Augenheilk. 193 (1988)

**Reporting customer complaints and return of product:**

Customer complaints including quality complaints, adverse events and other medical device related observations should be reported to 1stQ without delay. A report describing the details of the complaint/event, the applied therapy, the product type, LOT/serial number of the medical device used is requested.

If possible, return the medical device and/or its original container and/or any part of the packaging, as well as the used injection instrument to 1stQ or to your local distributor.

**Symbols used:**

	Do not re-sterilize		Serial number
	For single use		Sterilized using ethylene oxide
	Keep away from sunlight		Do not use if package is damaged
	Keep dry		Manufacturer
	Use by (date)		CE certified
	Consult Instructions for use		

**Liability:**

1stQ does not bear any responsibility 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.

This product is subject to change with or without prior notice. Improvement changes may be made in specification, shape and material.

All translations of this text are derived from the original English text. Should you face any discrepancy or problem in interpretation, please consult the English version for guidance.

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**Manufacturer:**



**1stQ GmbH**      Tel: +49 621 7895 3790  
 Harrlachweg 1      Fax: +49 621 7895 3791  
 68163 Mannheim      www.1stq.eu  
 Germany      info@1stq.de