



Instruction for use – monofocal refractive aspheric hydrophilic acrylic toric intraocular lenses for implantation into the capsular bag

Content:

One sterile aspheric toric intraocular lens (IOL) consisting of highly purified hydrophilic acrylate with covalently bounded UV absorber. Some of the acrylate lenses are manufactured optionally with covalently bounded yellow chromophore as blue light filter. This is marked with Y in the product code.

Description:

This intraocular lens (IOL) 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.

The tolerance for the refractive power of a 1stQ monofocal intraocular lens is ± 0.25 D in the range < 25.0 D and ± 0.5 D in the range ≥ 25.0 D.

The optical properties and the dimensions of the lens are indicated on the labels on the primary and secondary packaging.

Toric lenses are manufactured of hydrophilic acrylic material and have a plus cylinder (Figure 1.). The toric IOLs of 1stQ are marked with 2 fine lines on the posterior surface of the IOL close to the haptic/optic junction to identify the flat meridian of the IOL.

Indications of use:

All monofocal refractive lenses of 1stQ - unless differently indicated on the folding box - are indicated for implantation into the capsular bag of the adult eye after removal of a cataractous lens by extracapsular cataract extraction including phacoemulsification.

Astigmatism might be corrected with a properly selected toric lens.

Contraindications:

There are not known contraindications to the implantation of an intraocular lens into the capsular bag.

Packaging:

The hydrated lens is held by a lens holder fixed in the plastic screw cap of a glass vial/plastic container containing sterile water.

The vial/container is packed in a sterile peel-pouch or sterile blister.

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

Sterilization:

This intraocular lens has been sterilized by steam after being packed under clean room conditions. Sterility is guaranteed only when the packaging is neither opened nor damaged. The applied sterilisation procedure is marked on the folding box.

Storage:

Store at room temperature.

Do not expose to direct sunlight.



Do not freeze.
Keep dry, protect from moisture/water.

Expiration:

Do not use this medical device after the expiry indicated on the carton/pouch/blister and the primary container.

The expiry date refers to the first day of the month of expiry.

Conditions of transportation:

Handle with care.

Warnings:

- Do not use if the sterilized package is 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.
- Do not use any hydrophilic acrylic lens if there is no fluid in the lens container.
- If the IOL has been stored below room temperature prior to implantation, a temporary opaqueness of the lens may occur. This physical reaction does not harm the lens material and clears after equilibration in each case.

Precautions:

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.

The accurate power calculation is the key to the success of the implantation.

Before performing the implantation the surgeon must read all the material provided by 1stQ for the correct handling and insertion of this implant.

- Misalignment of the flat meridian of the IOL with the steep axis of the cornea may compromise the astigmatic correction. Such misalignment can result from inaccurate keratometry, inaccurate marking of the cornea, inaccurate placement of the IOL during surgery, unanticipated, surgically induced change in the cornea or physical rotation of the IOL after implantation.
- To minimize this effect the surgeon should ensure an accurate preoperative keratometry and biometry and should take care that the toric IOL is properly oriented at the end of the surgery.

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

- one-eyed patient
- colour vision deficiencies
- bleeding disorders, retinal detachment, retinopathy of prematurity in the medical history
- 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
- diabetes including its complications, e.g. proliferative diabetic retinopathy
- anatomical variances e.g. difficult access to the eye (e.g. deep-set eyes), microphthalmos, extremely shallow anterior chamber, small myotic pupil
- 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
- zone laxity or dehiscence and potential phacodonesis and lens subluxation
- special cataract types, e.g. dense (brunescent) nuclear cataract, posterior polar cataract, white (mature cortical) cataract, cataract due to rubeola, non-age related cataract
- disorders of the choroid, retina and the optic nerve, e.g. choroidal hemorrhages, retinal detachment, macular degeneration, severe optic nerve dystrophy

Use of intraocular air/gas tamponade:

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.

Posterior capsule opacification (PCO):

PCO continues to be one of the most common postoperative complications associated with cataract surgery. The sharp edge design of this IOL creates an effective barrier against PCO and reduces the rate of PCO development. However it cannot be excluded, that some patients may experience clinically significant PCO after surgery.

Calcification of IOLs:

Several reports – almost exclusively in diabetic patients - describe the calcification of intraocular – mainly hydrophilic acrylic - lenses in the postoperative period.

Laser treatment:

Focus the laser beam precisely on the action site behind the lens. A laser beam focused on the implant itself will lead to a damage of the lens.

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.

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.

**Patient information:**

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.

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.

Handling:

- Check the label on the package to ensure that an unexpired, proper lens model with the necessary spherical equivalent and cylinder is selected.
- It is recommended to store the lens the day before implantation at room temperature.
- Open the pouch/blister at the marked end, take out the container.
- Check the consistency of the information (model, power and serial number) provided on the label affixed on the container, primary packaging and folding box.
- Ensure that the IOL model and power corresponds with the results of the preoperative biometry.
- Put aside the container with its water content. Hold the lens holder fixed to the screw cap vertically with the lens on the top.
- Thoroughly rinse the lens with sterile intraocular irrigating solution (BSS) before the implantation/loading the injector.

Implantation devices (recommendation):

For the implantation of a monofocal refractive aspheric hydrophilic acrylic toric intraocular lenses use the 1stInject 2.0HB instrument. In case of toric lenses with a spherical equivalent (SEQ) > 20.5 D use the 1stInject 2.4HB instrument.

Preparation prior to implantation:

The eye to be operated should be marked on its limbus in the following manner:

- Ensure that the limbus is dry before making these marks.
During the usual preoperative measures mark the horizontal (0° - 180°) axis of the cornea as the reference axis while the patient is in sitting position and is looking forward to avoid cyclotorsion.
- In the operating room mark the steep axis of the cornea while the patient is in supine position and has been prepared for the surgery.
- Mark the axis of the incision.
- Use operating microscope.

Implantation:

The toric IOLs of 1stQ are marked with 2 fine lines on the posterior surface of the IOL close to the haptic/optic junction to identify the flat meridian of the IOL which must be aligned with the steep axis on the cornea by turning the IOL in the capsule clockwise (Figure 2.).

Check the correct orientation of the marking lines after the removal of the viscoelastic material once again.

Figure 1. The optical properties of the toric lens

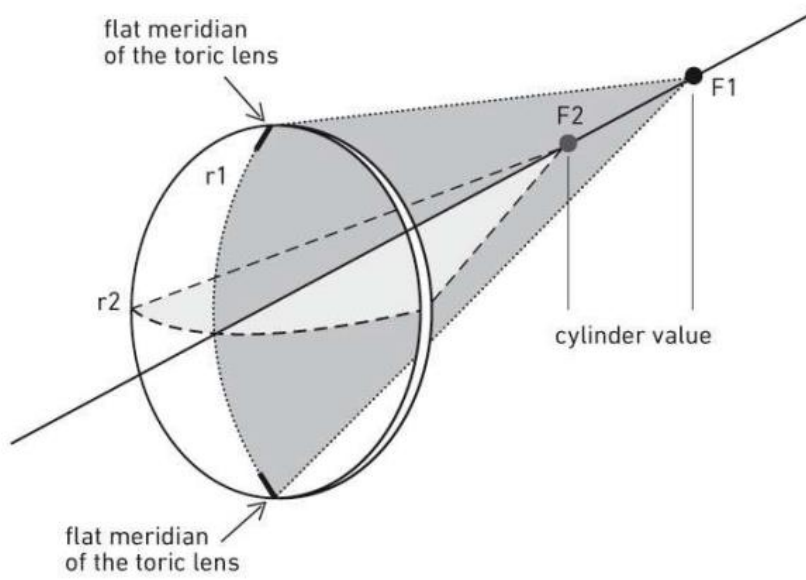
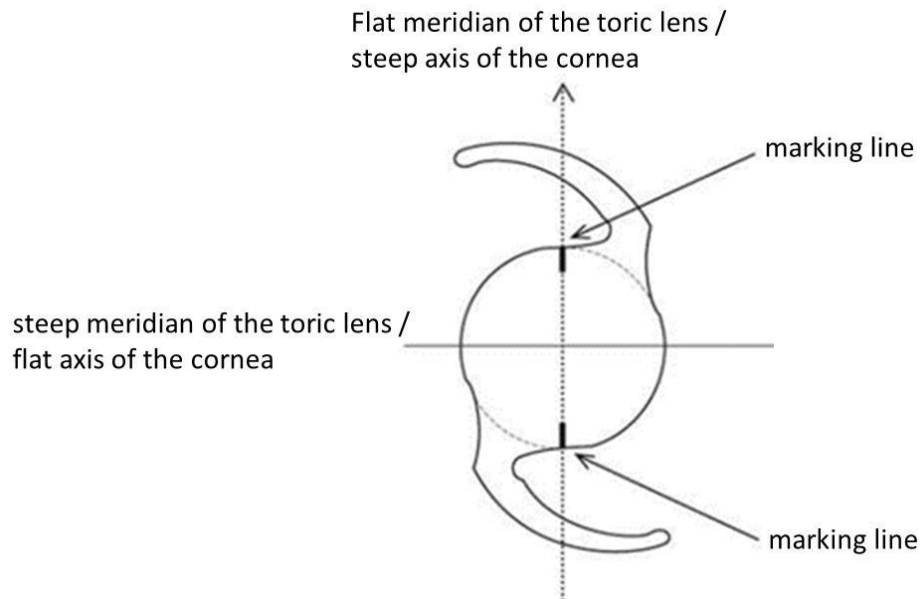


Figure 2. Positioning the toric lens in the capsular bag



Possible perioperative and postoperative complications and undesirable effects

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 - are referred in the relevant medical literature (see Reference below).

These may include, but are not limited to the following:

- corneal endothelial damage and/or oedema
- flat anterior chamber after lens extraction
- detachment of the Descemet's membrane
- wound leak/dehiscence
- thermal burns
- astigmatism, oedema/ bullous keratopathy
- uveitis
- haemorrhage in one or more segments of the eye
- radial tears of the anterior capsule
- rupture of the posterior capsule,
- capsular phimosis and capsule block syndrome,
- late tear of the capsule with posterior dislocation of the IOL,
- posterior capsule opacification,
- damage to the zonules with consequential IOL dislocation including the sunset syndrome,
- wound gape/iris prolapse, iris trauma, iris capture, epithelial ingrowth, pupillary block
- damage to the IOL during insertion,
- postoperative opacification of the IOL,



- incorrect positioning of the IOL during surgery,
- retinal detachment,
- vitreous loss,
- raised intraocular pressure (angle closure/open angle glaucoma),
- cystoid macular oedema,
- cyclitic membrane.

Following complications (not limited to these) may lead to a secondary surgical intervention:

- dissatisfactory visual outcome due to incorrect IOL refraction
- IOL dislocation (decentration, tilt, axial shift)
- pupillary block, iris capture
- wound leak
- retinal detachment

IOL power calculation:

The label of a 1stQ IOL contains the relevant optical parameters of the lens including the spherical equivalent power (SEQ).

Accurate keratometry and axial length determination are essential for a proper biometry, which is necessary for a successful visual outcome. It is essential that the measurements are carried out in a consistent manner using standardised settings.

Following parameters have impact on the variation in the calculated power of the selected lens:

- value of the corneal refractive index (US and majority of the world $n=1.3375$, in several parts of Europe $n=1.332$)
- eye model used
- IOL calculation formula applied during biometry
- method of keratometry
- measurement of the axial length

The A-constant given on the outer label of the IOL packaging should be used as the starting point for IOL power calculation. If available, use an optimised IOL-constant.

Reference:

- 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*
- <http://www.augenklinik.uni-wuerzburg.de/ulib/index.htm>

Reporting customer complaints including quality complaints, adverse events and other medical device related observations:

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.

**Return of product:**

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.

Contact for complaints:

1stQ GmbH
Quality Management
Harrlachweg 1
68163 Mannheim
Germany
Tel: +49 621 717 6330
Fax: +49 621 717 6333
E-Mail: info@1stq.de

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.

Several product types listed in this Instructions for use may not be marketed.












Please keep this Instructions for use and read it carefully before you apply this medical device. In case you are not in the possession of the Instructions for use, please request a copy.

Any national version has been translated from the core English text. Should you face any discrepancy or problem in interpretation, please use the English version for guidance.

Waste management:

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

Symbols used:

Nicht resterilisieren	
Nur für Einmalgebrauch (Nicht wieder verwenden)	
Von Sonnenlicht fernhalten	
Trocken aufbewahren	
Verwendbar bis (Datum)	
Gebrauchsanleitung beachten	
Seriennummer	
Sterilisiert mit Dampf oder Heißluft	
Bei beschädigter Verpackung nicht verwenden	
Hersteller	
CE-zertifiziert	


Hersteller:
 1stQ GmbH
 Harrlachweg 1
 68163 Mannheim
 0482 Germany

The content of this document is subject to change without prior notice.