Instructions For Use
1stQ Basis IOL

Toric progressive intraocular lens for implantation into the capsular bag

IFU available electronically on our website. Please visit: www.1stq.eu

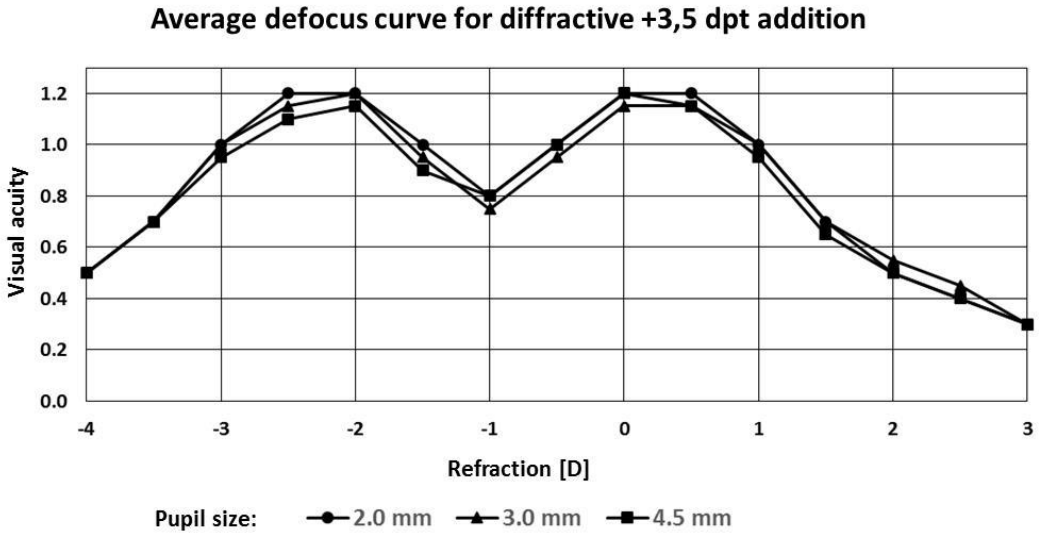
Content:
A sterile one-piece foldable toric progressive aspherical intraocular lens (IOL) for single use consisting of highly purified hydrophilic acrylate with covalently bound UV absorber. This IOL is manufactured optionally with additionally covalently bound yellow chromophore as blue light filter.

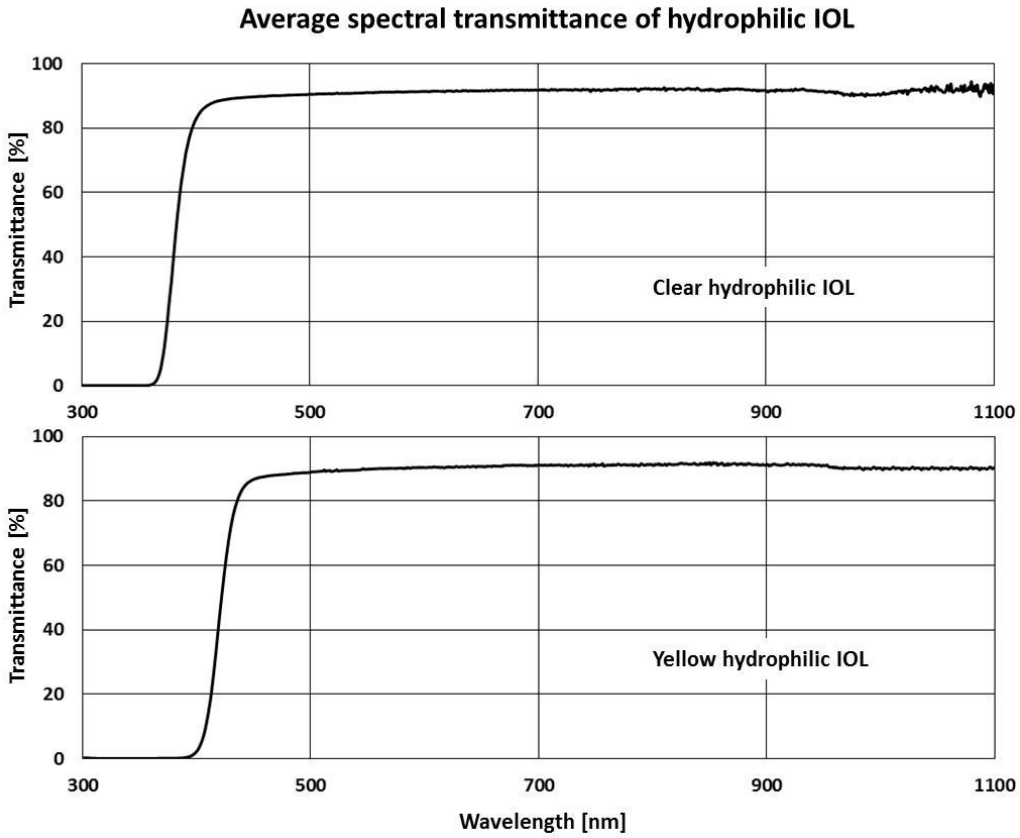
Description:
This IOL is an optical product of the highest precision. The manufacturing and the quality management system of 1stQ is in accordance with international standards and is certified according to ISO 13485 and 93/42/EEC.

The soft acrylic lens material is capable of being folded prior to implantation, allowing implantation through an incision smaller than the optic diameter of the IOL. After surgical insertion into the eye, the lens gently unfolds to restore the optical performance.

Toric Basis IOL have a plus cylinder and are marked with two fine lines on the posterior surface close to the haptic-optic junction to identify the flat meridian of the IOL (see below). The toric surface is on the posterior side, in case of a bitoric IOL on both sides.

The apodized diffractive part is on the anterior surface of the IOL.





The optical properties, e.g. refraction power (spherical equivalent for toric lenses), power of cylinder of toric lenses, added power of progressive lenses, as well as the dimensions of the lens, e.g. size of optics, total size of IOL, or haptic angulation (if applicable) 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.

Packaging:
Hydrophylic IOL are in 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 sterile product, a set of stickers for administrative purposes identifying the lens and a patient card to be completed and given to the patient.

Transport, storage and disposal:
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 of in accordance with local/national regulations and requirements.

Sterilization and expiry:
This IOL 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 and the date of expiry are indicated on the labels on the primary and secondary packaging. Do not use an IOL after its expiration date.

Indications of use:
All Basis IOL of 1stQ are indicated for 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 provides the necessary visual correction of an astigmatism and a pre-existing refraction error for the patient who additionally desires near, intermediate and distance vision with increased spectacle independence.

Contraindications:
Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list must be respected:

- individuals who drive at night for a living or whose occupation or hobbies depend on good night vision
- individuals who need very good near vision in semidarkness
- individuals who are professional or non-professional pilots
- patients who are happy wearing glasses

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
- extremely shallow anterior chamber
- severe corneal dystrophy
- zonular separation
- uncontrolled glaucoma
- diabetic retinopathy
- recurrent anterior or posterior segment inflammation of unknown etiology
- significant vitreous loss
- posterior capsular rupture
- severe optic nerve atrophy
- color vision deficiencies
- chronic uveitis
- clinically significant macular/RPE changes
- retinal detachment
- previous refractive patients
- keratoconus
- Age-related Macular Degeneration
- monocular patients or patients with reduced or lost vision in the other eye
- any eye disease in which postoperative visual acuity is not expected to be better than 0.5 (e.g. amblyopia, nystagmus, retinitis pigmentosa, aniridia, eccentric pupil)

- 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 eye (e.g. deepset 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
- zonular 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

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
- 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, incorrect positioning of the IOL during surgery
- unanticipated surgically induced change in the cornea, e.g. astigmatism, flat anterior chamber
- vitreous loss
- cyclitic membrane
- synechia
- wound gape, wound leak/dehiscence
- thermal burns

- damage to the IOL during implantation
- damage to anterior and posterior capsule (e.g. ruptures, tears) or to the zonules
- capsular phymosis and capsule block syndrome
- posterior capsule opacification (PCO)
- postoperative opacification/calcification of the IOL, deposits, discoloration, decoloration
- asthenopic discomfort, adaptional difficulties
- reduced best corrected visual acuity (distance)
- reduced contrast sensitivity
- reduced vision at night or in poor visibility conditions
- perception of halos or radial lines around point sources of light
- delayed neuroadaptation

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 are 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.
- Do not use any hydrophilic acrylic IOL if there is no fluid in the lens container.
- Do not use the storage fluid of a hydrophilic IOL.
- 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.

Some visual effects can be expected due to the superposition of the focused and unfocused images. These may include the perception of halos or radial lines around point sources of light under low lighting conditions. A reduction of contrast sensitivity as compared to a monofocal IOL may be experienced by some patients and may be more prevalent in low lighting conditions.
Therefore, patients should exercise caution when driving at night or in poor visibility conditions.
The physician should consider the following important aspects that are unique to the use of multifocal IOLs:

- The surgeon must target emmetropia to achieve optimal visual performance.
- Patients with significant preoperative (determined by keratometry) or expected postoperative astigmatism ≥ 1.0 D may not achieve optimal visual outcome without additional toric correction.
- Care should be taken to achieve IOL centration, as a decentration may result in visual disturbances under certain light conditions.
- Patients with pupil size less than 2.5 mm may not experience any near vision addition.

Patients may require a neuroadaptation period up to approximately 6 months to experience full visual benefits of the implanted multifocal function.

Preoperative calculation of IOL power:
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. Calculation may need the contribution of properly qualified optometrists. It is essential that the measurements are carried out in a consistent manner using standardized settings.
The label of a 1stQ IOL contains the relevant optical parameters of the lens, including the added power 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

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.

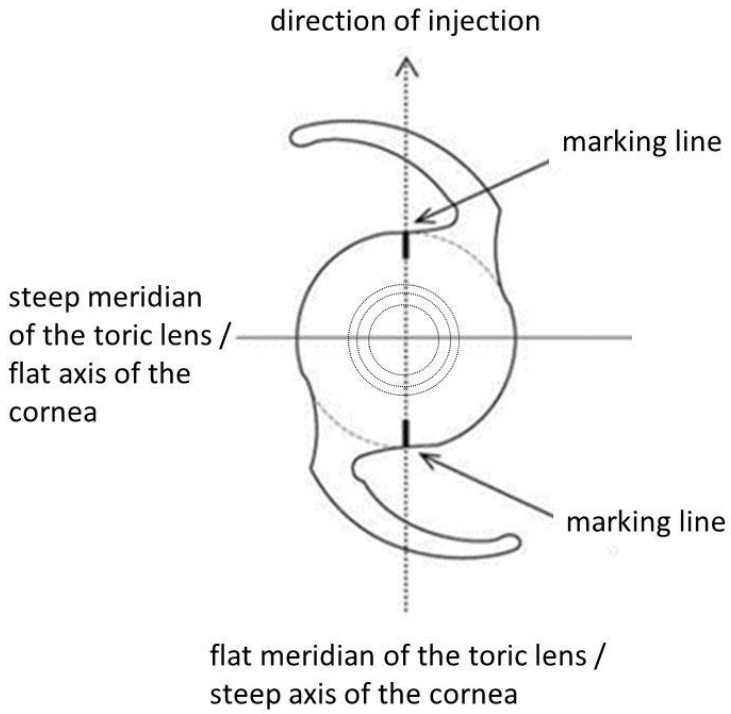
Misalignment of the flat meridian of the toric function may compromise the astigmatic correction. Such misalignment can result from inaccurate pre-operative keratometry/biometry, inaccurate marking of the cornea, inaccurate placement of the IOL during surgery, unanticipated surgically induced change 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 placed and oriented at the end of the surgery.

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.

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.



- 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.
- For the implantation of the IOL use the 1stInject 2.0HB instrument. In case of a spherical equivalent (SEQ) > 20.5 D use the 1stInject 2.4HB instrument. Check its expiration date.
- Open the outer package to remove the protective peel-pouch or blister and verify that the IOL container information is consistent with the outer package labeling (power, model and serial number).
- In a sterile environment open the protective peel-pouch or blister and remove the lens container from the packaging
- Check the consistency of the information (model, power and serial number) provided on the label affixed on the container, primary packaging and folding box.
- Carefully open the container and remove the lens. Handle lenses carefully to avoid damage to the lens optics or haptics. Non-toothed, polished instruments must be used when handling the IOL. Do not grasp the optical area with forceps.
- Thoroughly rinse the lens with a sterile intraocular irrigating solution (BSS).
- Examine the IOL for defects or foreign material.

- Carefully load the lens to an appropriate injection device; avoid any trapping or damaging of the lens optic or haptics. For loading and injection of the lens follow the Instructions for Use of the injector.
- Hydrophilic IOLs should not be kept in open air for longer than 1 minute. Neither type of IOL should be in folded condition for longer than 3 minutes. If these time limits have been exceeded the lens should be discarded.
- Inject the lens 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.
- Discard the injector after use.
- The surgeon must achieve perfect placement, orientation and centration in the capsular bag and emmetropia, for optimal results.
- Carefully remove all viscoelastic material from both sides of the lens. Residual viscoelastic material may cause complications including lens rotation resulting in the misalignment of the IOL, which compromises astigmatic correction. Check the correct orientation of the marking lines after the removal of the viscoelastic material once again.

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 Opthalmologists, 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 Ophthalmolgists & Biometrists. Third Edition, 1990
Holladay J. A Three-part System for Refining Intraocular Lens Power Calculations. J. Cataract Refract. Surg. V14: 17-24. 1988
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. Opthalmology 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 resterilize		Serial number
	For single use		Sterilized using steam or dry heat
	Keep away from sunlight		Do not used 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.

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

Manufacturer:

1stQ GmbH
Harrlachweg 1
68163 Mannheim
Germany

Tel: +49 621 7895 3790
Fax: +49 621 7895 3791
www.1stq.eu
info@1stq.de