Instructions For Use

Monofocal refractive hydrophilic preloaded acrylic sterile intraocular lens for implantation into the capsular bag

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

Content:
One sterile preloaded foldable intraocular lens (IOL) for single use consisting of highly purified hydrophilic acrylate with covalently bound UV absorber. Some of the acrylic lenses are manufactured optionally with covalently bound 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.

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

Indications of use:
All 1stQ Basis IOL – unless differently stated 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.

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

Packaging:
The hydrated hydrophilic IOL is in an IOL holder fixed in the plastic container containing sterile water. The container is sealed with an aluminium lid. The wet container is placed in a secondary sterile blister.
The overall packaging contains the medical leaflet, a set of stickers for administrative purposes identifying the product 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. The sterility indicator on the Tyvek lid of the secondary blister changes its colour after sterilization by steam from pink to brown.

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.

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 last day of the month of expiry.

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 hydrophilic IOL if there is no fluid in the lens container.
- If a hydrophilic 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.

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

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

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:
- 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 or 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 haemorrhages, 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 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.

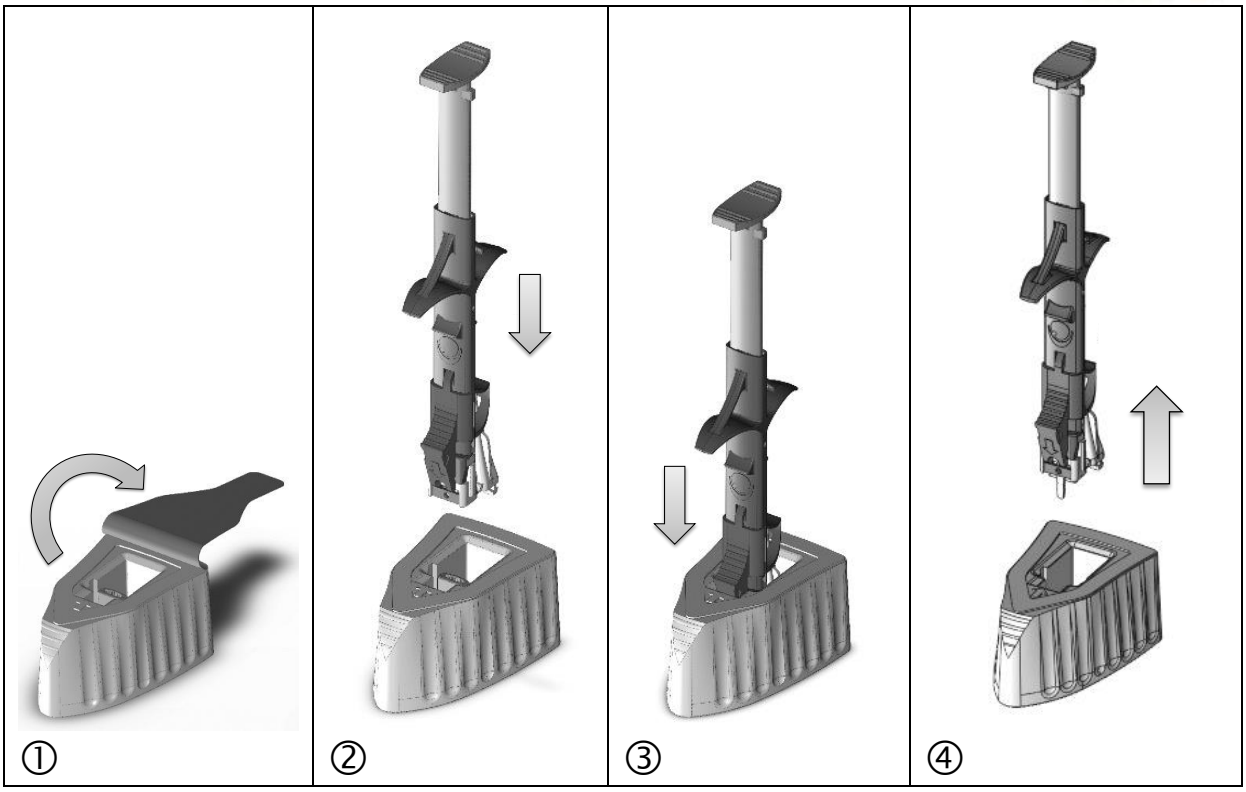
Handling:

- Check the label on the package to ensure that an unexpired, proper lens model with the necessary power is selected.
- Also the proper, unexpired injection system must be present.
- It is recommended to store the lens one day before implantation at room temperature.
- Open the pouch/blister at the marked end and take out the container under aseptic conditions.
- 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.
- Aseptically transfer the body of the injector, the relevant viscoelastic material and the sterile container with preloaded lens inside to the sterile area of the operating theatre.
- Do not damage the lens.
- Inject the lens using constant and uninterrupted pressure.
- For injection of the lens follow the Instructions for use of the **1stInject P2.2** single use injection system.

Implantation devices:
For implantation of a monofocal preloaded hydrophilic IOL use the **1stInject P2.2** injector. Follow the Instructions of Use of the **1stInject P2.2** single use injection system.

Description of figures:

1. Open the wet container.
2. Insert the injector into the wet container.
3. Push the injector down with a firm motion (until the "click").
4. Pull out the injector and check if the lens holder is loaded in the injector.
5. Fold up the cartridge nozzle (second „click”).
6. Push the anchor to the end position (third “click”).
7. Fill the chamber with viscoelastic solution approximately to the half of the nozzle.
8. Push the rod forward until the lens exit the cartridge.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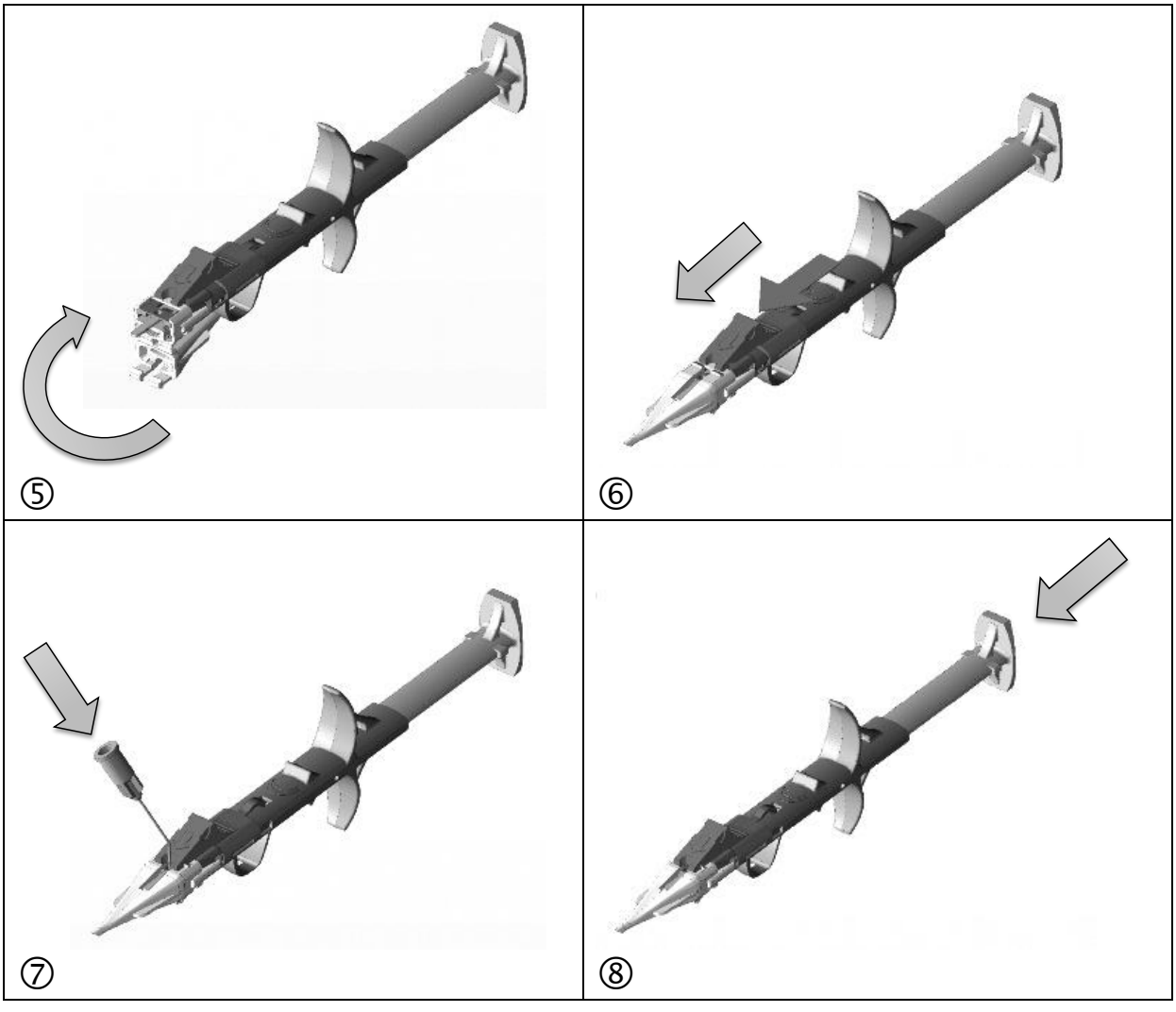
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Possible pre-, peri- and postoperative complications and undesirable effects:
As with any surgical procedure, there is risk involved.
The most common potential complications and undesirable effects accompanying cataract or implant surgery – some of them may lead to a secondary surgical intervention – are referred in the relevant medical literature. 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 phymosis 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, seclusio pupillae, iris capture, epithelial ingrowth, pupillary block
- damage to the IOL during insertion
- postoperative opacification/calcification 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
- hypopyon
- endophthalmitis
- IOL dislocation
- pupillary block
- corneal (stromal) oedema
- iritis

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

- dissatisfactory visual outcome, e.g. due to incorrect IOL refraction
- IOL dislocation (decentration, axial shift, rotation, tilt)
- 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.

Accurate up-to-date and complete keratometry, biometry (axial length, anterior chamber depth, corneal radii) and visual acuity (s.c./c.c. and subjective refraction) are inevitable for a successful

visual outcome. It is essential that the measurements are carried out in a consistent manner using standardized settings.
The surgeon should preoperatively determine the optimal power of the lens to be implanted according to his experience, preference and intended location. Calculation may need the contribution of properly qualified optometrists.

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 optimized IOL-constant. Please visit:
http://www.augenklinik.uni-wuerzburg.de/ulib/index.htm

References:
Holladay JT: Standardizing constants for ultrasonic biometry, keratometry and intraocular lens power calculations. JCRS 1997, 23(9), 1356-70
Cataract Surgery Guidelines - The Royal College of Ophthalmologists, London, September 2010
Güell JL et al: Phakic intraocular lenses Part.1-2. JCRS 2010, 36(11) 1976-93 and 36(12) 2168-94

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 is requested describing the details of the complaint/event, the applied therapy, the product type and LOT/serial number of the medical device used.

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

Contact details for complaints:
1stQ GmbH
Quality Management
Harrlachweg 1
68163 Mannheim
Germany
Tel: +49 621 7895 3790
Fax: +49 621 7895 3791
E-Mail: info@1stq.de
Homepage: www.1stq.eu

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.

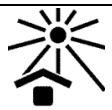
This product is subject to change with or without prior notice. Improvement changes may be made in specification, shape and material.

Please keep these instructions for use and read it carefully before you apply this medical device. IFU is also available electronically on our website: www.1stq.eu.

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

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.

Symbols used:

	Do not resterilize
	For single use
	Keep away from sunlight
	Keep dry
	Use by (date)
	Consult Instructions for use
	Serial number
	Sterilized using steam or dry heat
	Do not used if package is damaged
	Manufacturer
	CE certified

Manufacturer:

1stQ GmbH
Harrlachweg 1
68163 Mannheim
Germany

www.1stQ.de