1stQ E-IFU

1stQ "BASIS" HYDROPHOBIC TORIC INTRAOCULAR LENSES PRELOADED IN A SINGLE USE INJECTOR EN

INSTRUCTIONS FOR USE

DESCRIPTION

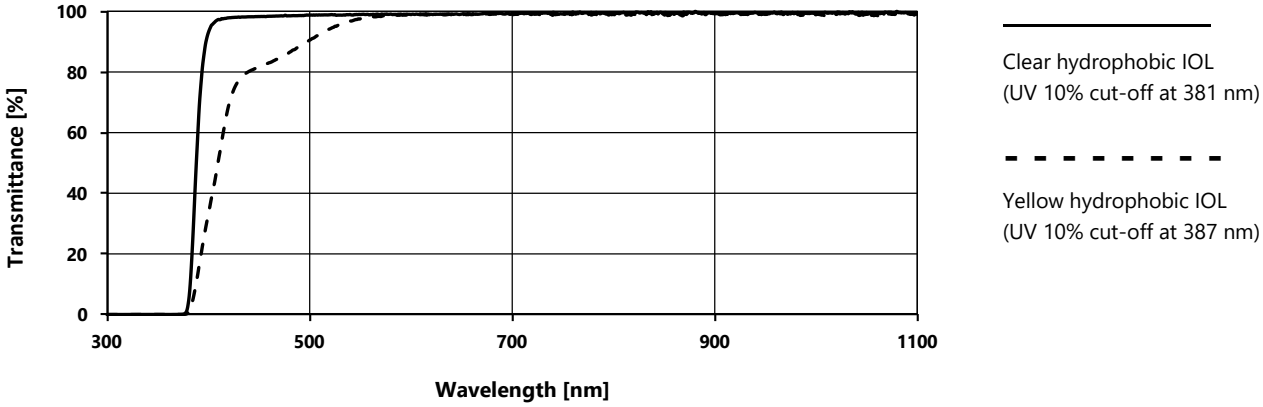
Consists of one, single piece, sterile, foldable acrylic intraocular lens (IOL) with UV-absorbent, preloaded in an assembled injector. Yellow IOLs have a blue-light filtering chromophore covalently bonded to the material (see Graph 1). These models are marked with 'Y' in the product code. Different models are controlled individually for their optical and mechanical properties.

Injector parts: injector body, adapter, rotatable ring, cartridge, stopper, plunger with a soft tip, spring.

Toric models: In case of monotoric lenses the toric surface is on the posterior side.

EDOF (Extended Depth of Focus) lenses carry an additional optical function on the central portion of the anterior surface of the otherwise monofocal optic as a wavefront-shaping element in order to create an extended focal range.

Graph 1: Average spectral transmittance of 1stQ IOLs



MODELS

Model	Material	Design	Estimated corneal incision size
B1TB00 S1TB00	hydrophobic	toric	2.2 mm
B1TBY0 S1TBY0	hydrophobic	toric	2.2 mm
B1ZBY0 S1ZBY0	hydrophobic	EDOF toric	2.2 mm

DEVICES INTENDED FOR USE TOGETHER WITH THE IOL

The preloaded IOL should be implanted with a suitable viscoelastic solution. A compatibility chart can be found on our website: www.1stq.eu/compatibility.Ophthalmic Viscosurgical Devices other than those listed in the chart have not been tested and cannot be recommended.

PACKAGING

The IOL is packaged in the injector and the entire system is packaged in a protective blister, sterilized by ethylene oxide.

EXPIRATION DATE

1stQ IOLs are sterile unless their sterile barrier system is damaged. The expiry date is printed on the labels of the outer packaging and the protective blister. Do not use an IOL after its expiration date.

INTENDED PURPOSE

1stQ IOLs Posterior Chamber Intraocular Lenses are intended for primary implantation into the capsular bag in the posterior chamber of the eye to replace the human crystalline lens in adult patients.

MEDICAL INDICATION

1stQ POSTERIOR CHAMBER Intraocular Lenses are indicated for visual correction of aphakia secondary to removal of the crystalline lens in adult patients

Toric models: 1stQ toric IOLs are indicated for patients with corneal astigmatism who aspire to have improved uncorrected distance vision and reduction of residual refractive cylinder.

EDOF toric models: 1stQ EDOF toric IOLs are indicated for patients with corneal astigmatism who aspire to have improved intermediate vision with uncompromised distance vision and reduction of residual refractive cylinder.

PATIENT TARGET GROUP

Aphakic adult patients (18 years old and older)

INTENDED USERS

1stQ IOLS must be handled and implanted by a qualified and properly trained ophthalmic surgeon

CONTRAINDICATIONS

There are no known contraindications to the use of 1stQ Posterior Chamber IOL when used as recommended.

PRECAUTIONS

The safety and effectiveness of 1stQ IOLs have not been studied in patients with certain existing conditions and /or intraoperative complications listed below (as these patients were excluded from clinical studies). Careful preoperative and perioperative evaluation and clinical judgement should be made by the ophthalmic surgeon to decide the risk/benefit ratio before the implantation in the following (non-exhaustive) pre-existing conditions:

- Perioperative complications such as posterior capsular rupture, zonular separation or damage, significant vitreous loss, significant anterior chamber bleeding or choroidal hemorrhage
- Extremely shallow anterior chamber

- Severe corneal dystrophy
- Severe optic nerve atrophy
- Color vision deficiencies
- Uncontrolled intraocular pressure or glaucoma
- Recurrent anterior or posterior segment inflammation of unknown etiology
- Diabetic retinopathy
- Iris neovascularization
- Previous retinal detachment
- Clinically significant macular or Retinal Pigment Epithelium changes
- Amblyopia
- Pseudoexfoliative syndrome
- Polaris posterior cataract
- Zonulolysis
- Phakodonesis
- Current or previous use of systemic alpha-1a adrenergic antagonist (especially tamsulosin)
- Pregnancy
- Choroidal hemorrhage
- Retinal detachment
- Bacterial or viral endophthalmitis

TORIC MODELS

- Irregular astigmatism
- In case of patients who underwent previous refractive treatment – for example any kind of keratoplasty – the indication should be determined very carefully.

COMPLICATIONS

As with any surgical procedure, there is risk involved. The following non-exhaustive list specifies the complications that have been associated with the implantation of IOLs:

Disease related

- Corneal damage or edema
- Secondary glaucoma

Postoperative

- Intraocular infection
- IOL replacement or extraction
- Uveitis
- Cystoid macular edema
- Damage to the zonules or to the capsule with consequential IOL dislocation
- Posterior capsule opacification (PCO)
- Postoperative opacification/calcification of the IOL
- Asthenopic discomfort, adaptional difficulties
- Reduced contrast sensitivity
- Reduced vision at night or in poor visibility conditions
- Perception of halos or radial lines around point sources of light

- Dissatisfactory visual outcome due to incorrect IOL refraction
- Macular degeneration leading to blindness in long term (years)
- TASS, endophthalmitis

WARNINGS

- 1stQ IOLs are designed to be implanted into the capsular bag only. There is no clinical data demonstrating the safety and efficacy of an implantation in the ciliary sulcus.
- Examine the package labels carefully for information about the lens model, power, and expiration date. Lenses should not be used after the expiration date.
- Do NOT re-sterilize or re-use the lens or any part of the system by any method.
- Do NOT USE the IOL if the packaging is damaged or wet and lens sterility may have been compromised.
- DO NOT USE the product if the package was unintentionally opened before use.
- Store the unopened IOL box in a dry place, away from moisture and direct sunlight at 15-35°C.
- A high level of surgical skills is required to implant intraocular lenses. The ophthalmic surgeon should have observed and/or assisted at numerous implantations and successfully completed one or more courses on IOL implantation before attempting to implant intraocular lenses.
- IOLs should be handled carefully to avoid damage to the lens optics or haptics. Non-toothed, polished instruments should be used, without grasping the optical area with forceps.
- Patients should be advised that unexpected outcomes may necessitate additional surgical intervention.
- Patient should be advised to wear spectacles in the sunlight to avoid damage by ultraviolets rays.
- For optimal results, aim to achieve perfect IOL centration.
- The product or its waste material should be disposed of in accordance with local/national regulations and requirements.
- Use of intraocular gas/air tamponade: Deterioration in the transparency of the IOL has been observed upon the intraocular administration of SF6 or C3F8 gases. Visually significant haze may develop, potentially leading to an IOL exchange.

TORIC MODELS

- Prior to surgery mark the operative eye with at least two reference points (while the patient is in the sitting position) or use an operating microscope that provides an axis guide.
- For optimal results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The posterior surface of the IOL is marked with 2 linear indentations at the optic-haptic junctions that identify the flat meridian of the IOL. The cylinder axis marks should be aligned with the post-incision steep corneal meridian.
- 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.

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.

PREOPERATIVE CALCULATION OF IOL POWER

IOL power should be determined preoperatively based on proper biometry data using the formula available in the literature. 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 post-operative results.

For Toric IOLs, the use of a computerized/web-based toric calculator is highly recommended to ensure the best optical outcome.

For further information please refer to http://www.1stq.eu.

DIRECTIONS FOR USE

1. Open the outer package to remove the blister containing the injector system with the IOL and verify that the information on the blister is consistent with the outer package labeling (e.g. power, model, SN).

2. Open the blister and remove the injector system with the IOL in a sterile environment.

3. Fully introduce the cannula (23-27G) of a syringe filled with viscoelastic material into the small aperture indicated with '1' (Fig. 1) until it is completely inserted into the blue funnel. Maintain a slight pressure on the cannula tip while injecting the viscoelastic solution through the aperture. The injected quantity of OVD is sufficient as soon as the OVD has reached the end of the IOL haptics (appr. 0.2-0.25 ml).

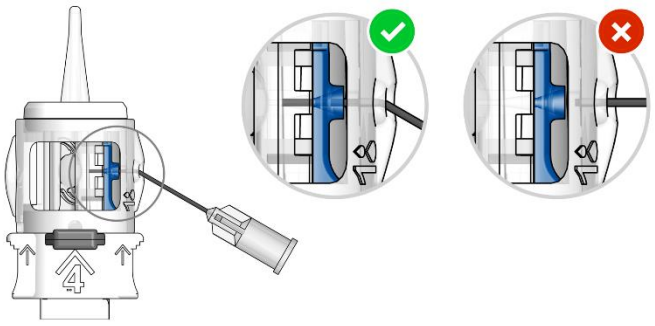


Fig. 1

4. Check the lens position in the cartridge, make sure that the haptics are safely located within the guiding rails of the cartridge.

5. 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" (Fig. 2a).

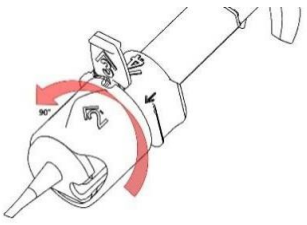


Fig. 2a

6. Remove the red stopper indicated with '3' by pulling and discard it (Fig. 2b).

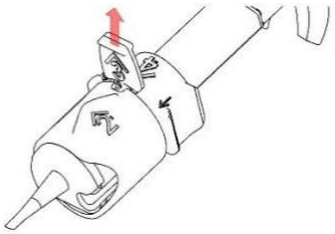


Fig. 2b

7. Remove the adapter together with the rotatable ring as indicated by '4' (Fig. 3) by pulling it off and discard it.

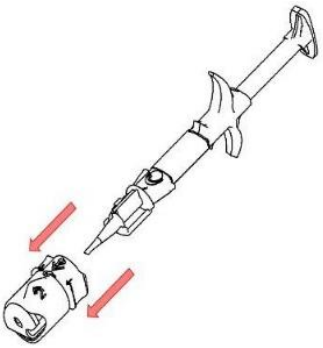


Fig. 3

8. Push the plunger forward a few millimeters until the OVD reaches the end of the nozzle tip to activate the coating in the nozzle (Fig. 4a, 4b). Make sure that the IOL remains in the cartridge and it is not advanced into the nozzle (Fig. 4c).

9. Keep the injector in this state for 30 seconds.

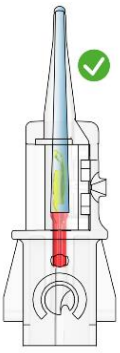


Fig. 4a

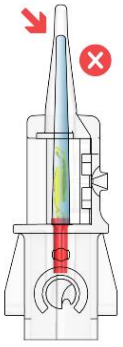


Fig. 4b

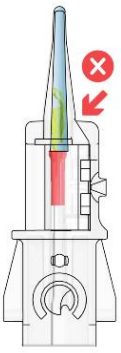


Fig. 4c

10. With the nozzle tip bevel facing down, inject the IOL applying continuous light pressure on the plunger, and do not pause until the optic exits the cartridge tip.

11. Once the lens optic exits the cartridge tip, stop pressing and let the trailing haptic follow the optic.

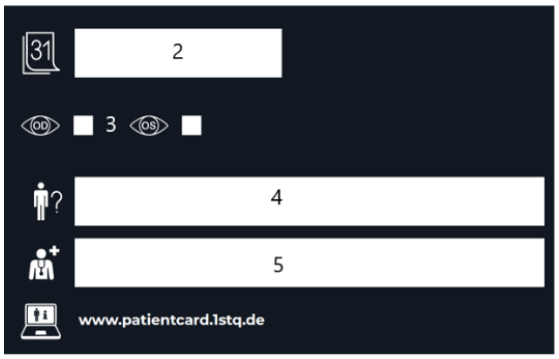
12. Carefully withdraw the cartridge nozzle from the eye once the injection process is completed.

NOTE

- Balanced Salt Solution alone should not be used as lubricant.
- When pressing the plunger, too much resistance may indicate a trapped lens.
- If you had already advanced the IOL into the nozzle before proceeding to step 9, you could expect increased injection force or a blocked IOL. In this case, try to push the IOL forward immediately at a moderate pace for a successful ejection.
- Do not stop the injection after you have started implanting the lens. The injection process should be one continuous process without interruption.
- If the IOL blocks the injector, discard the injector and the IOL.
- Discard the injector after use.
- The product or its waste material should be disposed of in accordance with local/national regulations and requirements.

IMPLANT CARD AND PATIENT INFORMATION

One of the self-adhesive labels with the IOL data and UDI 2D barcode printed on it is designed to be placed on the Implant Card, also enclosed in the packaging. This Patient Card should be handed over to the patient for future reference allowing the patient to identify the surgeon and the type of IOL implanted.
The implant card has to be filled in by the healthcare facility / healthcare provider as follows:



1. Place the label with UDI 2D barcode on the Implant card.
2. Fill in the date of implantation
3. Mark the implanted eye - left (OS) or right (OD).
4. Fill in the name of patient or patient ID.
5. Fill in the name and address of the healthcare institution / provider.
6. Fill in the medical device name.

The link to access the patient information is printed on the implant card.

SYMBOLS – IMPLANT CARD

Patient Name or patient ID	Date of implantation	Name and Address of the implanting healthcare institution/provider
Name and Address of the manufacturer	Information website for patients	Device Name
Serial Number	Unique Device Identifier	Right Eye
Left Eye		

SYMBOLS - PACKAGING

CE certified	Keep dry	Do not re-use
Keep away from sunlight	Consult instructions for use	Do not re-sterilize
Serial Number	Use by date	Sterilized using ethylene oxide
Do not use if package is damaged	Manufacturer	Sterile barrier system with protective packaging inside
Temperature limit	Date of manufacture	Caution
Medical device	Unique Device Identifier	

MANUFACTURER

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Any adverse event that the lens may have caused, any serious incident should be reported to 1stQ's Quality Assurance at info@1stq.de and to the competent regulatory authority.

LAST UPDATE: December 2023 Revision number: 01

This document is executed in the English language. In the event of any inconsistencies, the English version shall prevail.