1stQ E-IFU

1STQ POSTERIOR CHAMBER INTRAOCULAR LENSES INSTRUCTIONS FOR USE EN

DESCRIPTION

Consists of one, single piece, sterile, foldable acrylic intraocular lens (IOL) with UV-absorbent. 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.

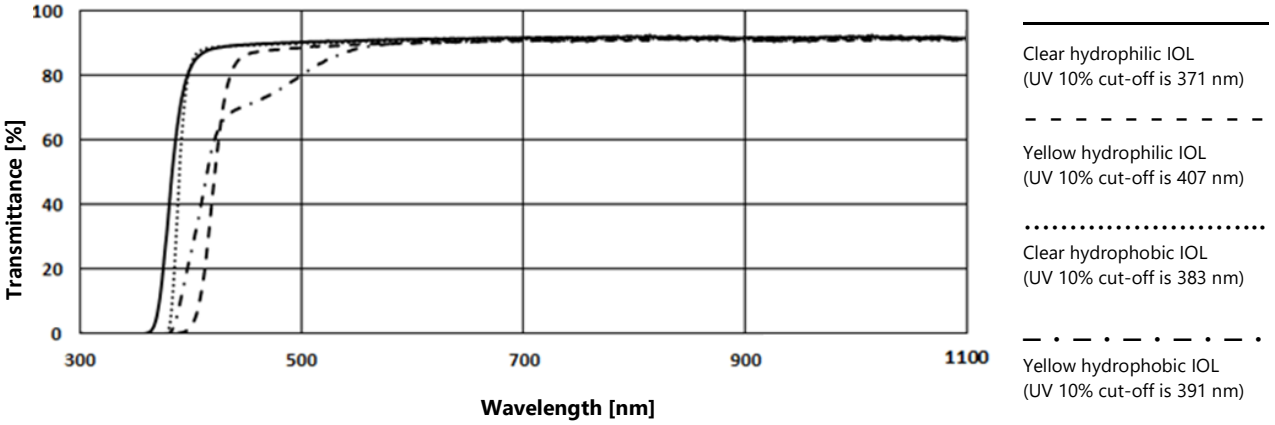
Toric models: In case of monotoric lenses the toric surface is on the posterior side, whereas in case of bitoric lenses both sides are toric.

Trifocal models: The anterior surface is the apodized, diffractive side of the lens. The added power for near vision is indicated on the label. For the MTF Through Focus curve see Graph 2.

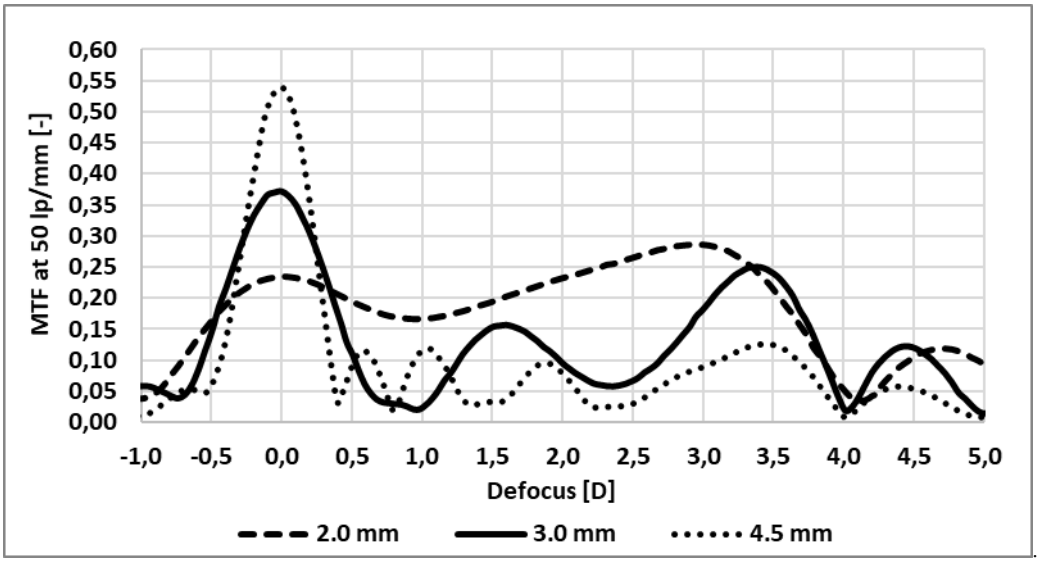
Trifocal-toric models: both Toric and trifocal descriptions are valid for the models.

EDOF (Extended Depth Of Focus) models: EDOF lens 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



Graph 2: MTF Through Focus Response at 50 lp/mm for 2.0, 3.0 and 4.5 mm aperture



MONOFOCAL MODELS

Code	Material	Design
S1AW00 B1AW00	hydrophilic	monofocal
S1AWY0 B1AWY0	hydrophilic	monofocal
B2AW00 S2AW00	hydrophilic	monofocal
B2AWY0 S2AWY0	hydrophilic	monofocal
611HPS	hydrophilic	monofocal
601HP	hydrophilic	monofocal
B1AD00	hydrophobic	monofocal
B1ADY0 S1ADY0	hydrophobic	monofocal

TORIC MODELS

Code	Material	Design
B1TWYT S1TWYT B1TWY0 S1TWY0	hydrophilic	toric
S1BWY0	hydrophilic	Bi-toric

TRIFOCAL MODELS

Code	Material	Design
S1EWYN B1EWYN	hydrophilic	trifocal
S2EWYN B2EWYN	hydrophilic	Trifocal

TRIFOCAL-TORIC MODELS

Code	Material	Design
B1HWYN S1HWYN	hydrophilic	trifocal toric

EDOF MODELS

Code	Material	Design
877EBY	hydrophobic	EDOF

DEVICES INTENDED FOR USE TOGETHER WITH THE IOL

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

PACKAGING

Hydrophilic lenses are supplied steam sterilized in a vial or plastic vessel filled with sterile water. Hydrophobic lenses are supplied dry, packaged in a plastic lens case, sterilized by ethylene oxide. The containers are protected by blister or peel-pouch.

EXPIRATION DATE

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

INTENDED PURPOSE

1stQ 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.

TRIFOCAL MODELS

1stQ Trifocal IOLs are indicated for patients who aspire to have near, intermediate and distance vision with increased spectacle independence.

TRIFOCAL-TORIC MODELS

1stQ Trifocal-toric are indicated for patients with corneal astigmatism who aspire to have near, intermediate and distance vision with increased spectacle independence and reduction of residual refractive cylinder.

EDOF MODELS
1stQ EDOF IOLs are indicated for patients who aspire to have improved intermediate vision with uncompromised distance vision.

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
- Clinically significant macular or Retinal Pigment Epithelium changes
- Previous retinal detachment
- 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.

TRIFOCAL MODELS

- Keratoconus
- Age-related Macular Degeneration
- Monocular patients
- 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 with Any eye disease in which postoperative visual acuity is not expected to be better than 0.5 (e.g. nystagmus, retinitis pigmentosa, aniridia, eccentric pupil)

TRIFOCAL-TORIC MODELS

Precautions of Toric and Trifocal models are applicable for Trifocal-toric models

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

Preoperative

- Pupillary block
- Iris trauma
- Hemorrhage

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
- Endophthalmitis
- 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)
- Postoperative period
- 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 resterilize or reuse the lens 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.
- DO NOT USE hydrophilic IOLs if there is no fluid in the lens container.
- The storage fluid must not be used.
- A temporary opaqueness of the lens may occur in case of a considerable change of temperature.

This phenomenon does not damage the lens material and the lens reverts to transparency after some time.

- 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.

TRIFOCAL MODELS

- Manage patient selection and operative technique carefully to ensure that the total postoperative corneal astigmatism does not exceed 1.0 diopters. Patients with pupil size less than 2.5 mm may not obtain any near vision benefit.
- Some patients may experience reduced contrast sensitivity as compared to monofocal IOLs.
- Some patients may experience visual effects with the Trifocal IOLs because of the super-positioning of focused and unfocused images. Visual effects may include the perception of halos or radial lines around point light sources under low illumination conditions.
- Patients should be advised that unexpected outcomes could lead to continued spectacle dependence.

TRIFOCAL-TORIC MODELS

- Warnings of Toric and Trifocal models are applicable for Trifocal-toric models.

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.de.

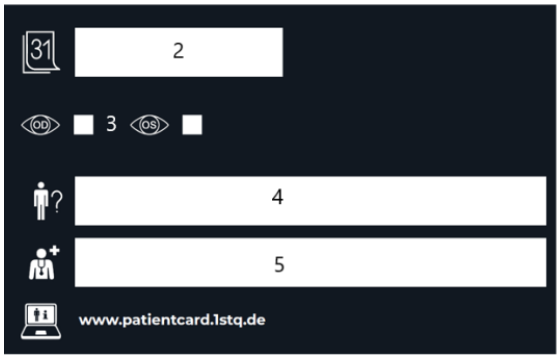
For trifocal lenses target emmetropia.

DIRECTIONS FOR USE

1. Open the outer package to remove the protective peel-pouch or blister pack and verify that the IOL container information is consistent with the outer package labeling (e.g. power, model, SN).
2. Open the protective peel-pouch or blister and remove the lens container from the packaging in a sterile environment.
   - Hydrophilic lenses: Hold the vial or vessel vertically. Carefully open the cap and remove the lens holder from the fluid.
   - Hydrophobic lenses: Open and remove the container cap to expose the lens.
3. Transfer the lens, using sterile equipment to an appropriate loading device. Rinse the IOL with sterile Balanced Salt Solution. For loading and injection of the lens follow the Instructions for Use of the injector.
4. Various surgical procedures can be utilized. The surgeon should select a technique that is appropriate for the patient.
5. 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.

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. Stick 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 device name.

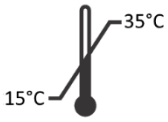
The link to access the patient information is printed on the implant card.

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 steam or dry heat
 Do not use if package is damaged	 Manufacturer	 Sterilized using ethylene oxide

 Temperature limit	 Date of manufacture	 Single sterile barrier system with protective packaging inside
 Medical device	 Unique Device Identifier	 Caution

MANUFACTURER

1stQ GmbH
Konrad-Zuse-Ring 23
68163 Mannheim
GERMANY

Tel: +49 621 7176330
Fax: +49 621 7176333
www.1stq.eu
info@1stq.de

Any adverse events 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: July 2021 Revision number: 01

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