1stQ E-IFU

1STQ "BASIS" PRELOADED HYDROPHILIC INTRAOCULAR LENSES INSTRUCTIONS FOR USE EN

DESCRIPTION

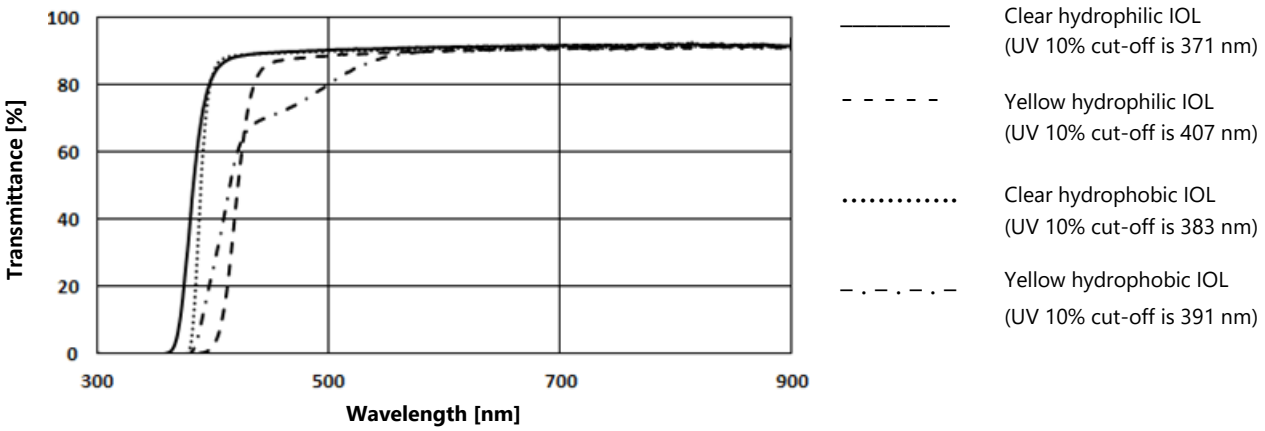
Consists of one, single piece, sterile, preloaded, foldable acrylic intraocular lens (IOL) with UV-absorbent. Yellow IOLs have a blue-light filtering chromophore covalently bonded to the material (see Graph 1). These models are marked with 'Y' in the product code. Different models are controlled individually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

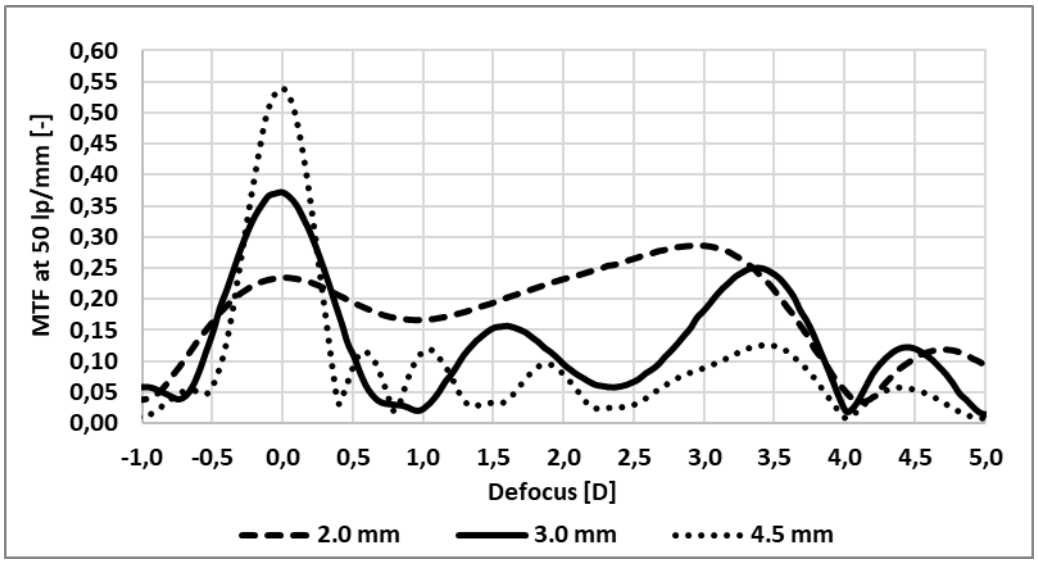
Trifocal models: The anterior surface is the apodized, diffractive side of the lens. The added power for near vision is indicated on the label. For the MTF Through Focus see Graph 2.

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

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



NOTE

1stQ Preloaded Hydrophilic Intraocular Lenses are dedicated for use uniquely with the 1st INJECT P2.2 or Medicel Accuject single use injector system as shown at the model table. The two major components (the IOL and the injector) of this preloaded injection system are packaged and sterilized separately. Before using the devices, please read both Instructions for Use carefully.

MONOFOCAL MODELS

Code	Material	Design	Compatible injector
B2AP00 S2AP00	hydrophilic	monofocal	1st INJECT P2.2
B2APY0 S2APY0	hydrophilic	monofocal	1st INJECT P2.2

TRIFOCAL MODELS

Code	Material	Design	Compatible injector
B7EP0N S7EP0N	hydrophilic	trifocal	1st INJECT P2.2
B1EP0N S1EP0N	hydrophilic	trifocal	Medicel Accuject 2.1 -1P / Medicel Accuject PRO 2.1 -1P
B1EPYN S1EPYN	hydrophilic	trifocal	Medicel Accuject 2.1 -1P / Medicel Accuject PRO 2.1 -1P
B2EPYN S2EPYN	hydrophilic	trifocal	Medicel Accuject 2.1 -1P / Medicel Accuject PRO 2.1 -1P

TORIC MODELS

Code	Material	Design	Compatible injector
B1TP0T S1TP0T S1TP00	hydrophilic	toric	Medicel Accuject 2.1 -1P / Medicel Accuject PRO 2.1 -1P
B1TPYT S1TPYT S1TPY0	hydrophilic	toric	Medicel Accuject 2.1 -1P / Medicel Accuject PRO 2.1 -1P

TRIFOCAL TORIC MODELS

Code	Material	Design	Compatible injector
B1TPYN S1TPYN	hydrophilic	trifocal-toric	Medicel Accuject 2.1 -1P / Medicel Accuject PRO 2.1 -1P

Products compatible with Medicel Accuject Pro 2.1-1P can be used with Medicel Accuject 2.1-1P after removing the loading chamber from the injector.

PACKAGING

The hydrophilic lenses are supplied steam sterilized in a container filled with sterile water. The containers are packed in a protective blister.

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 also 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 recommended for patients who aspire to have near, intermediate and distance vision with increased spectacle independence.

TRIFOCAL-TORIC MODELS

1stQ Trifocal-toric IOLs are also indicated for presbyopic patients who aspire to have near, intermediate and distance vision with increased spectacle independence and with corneal astigmatism.

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
- Diabetic retinopathy
- Iris neovascularization
- Clinically significant macular or Retinal Pigment Epithelium changes
- Previous retinal detachment
- Amblyopia
- Pseudoexfoliative syndrome
- Polaris posterior cataracta
- A. hyaloidea persistens
- 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 1.5 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 superpositioning 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.

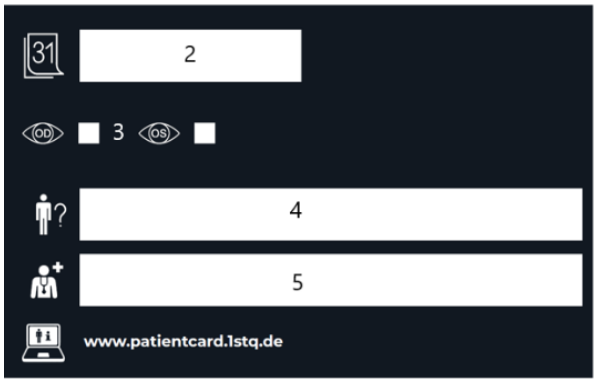
DIRECTIONS FOR USE

1. Open the outer package to remove the protective blister pack and verify that the IOL container information is consistent with the outer package labeling (e.g. power, model, SN). At the same time ensure that the appropriate, unexpired, sterile and unused 1st INJECT P2.2 injection system or Medicel Accuject 2.1 -1P / Medicel Accuject PRO 2.1 -1P (see the compatible injectors in the model table) is available.
2. Open the blister at the marked end and remove the lens container in a sterile environment.
3. Remove the peel-off aluminum foil from the wet lens container while holding the container horizontally.
4. For loading and injection of the lens please refer to the Instructions for Use enclosed with the 1st INJECT P2.2 or Medicel Accuject 2.1 -1P / Medicel Accuject PRO 2.1 -1P injection system.

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:



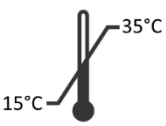
1. Stick the label with UDI 2D barcode on the Implant card.
2. Fill in the date of implantation.
3. Mark the implanted eye - left (OS) or right (OD).
4. Fill in the name of patient or patient ID.
5. Fill in the name and address of the healthcare institution / provider.
6. Fill in the device name.

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		Single sterile barrier system with protective packaging inside
	Temperature limit		Date of manufacture		Caution

MD	Medical device	UDI	Unique Device Identifier	

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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.

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