



1stQ E-IFU

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BASIS IOL HYDROPHILIC INTRAOCULAR LENS

INSTRUCTIONS FOR USE

EN

DESCRIPTION

Single piece, sterile, foldable acrylic aspheric hydrophilic posterior chamber intraocular lens (IOL) with UV-blocker. The IOL material is 100% hydrophilic acrylic random copolymer based on hydroxyethyl methacrylate and ethoxyethyl methacrylate, with covalently bound UV blocker, with a water content of 25%. Yellow IOLs have a light filtering chromophore with a **UV Cutoff <2% at 400 nm**, covalently bonded to the material (see Graph 1). These models are marked with 'Y' in the product code.

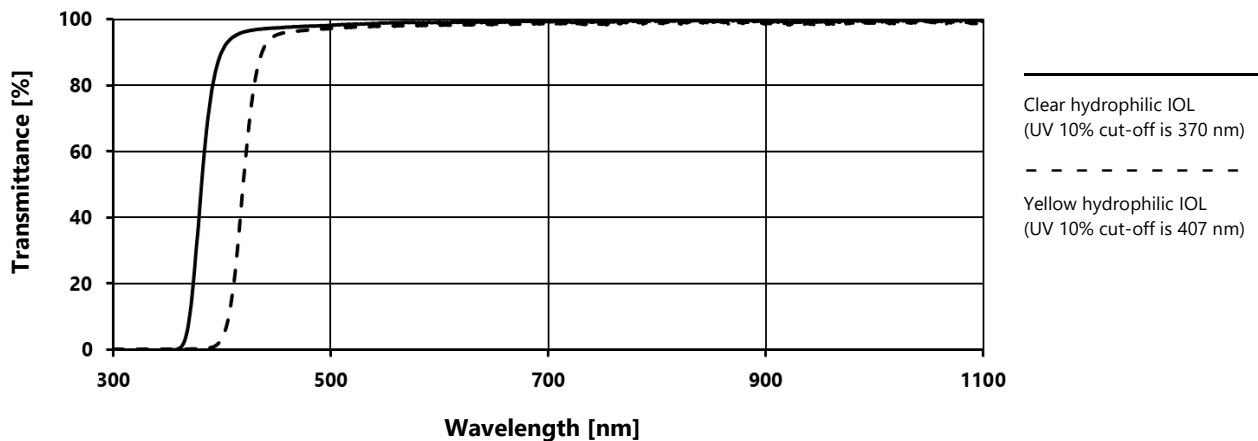
The optic can be monofocal, trifocal, monofocal toric or trifocal toric. The IOL is non-preloaded, it has to be manually loaded into a compatible injector. Different models are controlled individually for their optical and mechanical properties.

Monofocal 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. MTF values in the graph describe the lens' optical performance in a standardized eye model as the focus is gradually shifted from that of a far object to increasingly near objects. Higher numbers indicate better performance.

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

Graph 1: Average spectral transmittance of 1stQ hydrophilic IOLs



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MODELS

| Product name | Model | Material | Design |
|--|----------------------------|-------------|-----------------|
| Posterior chamber intraocular lens, pseudophakic, hydrophilic | B1AW00 S1AW00 | hydrophilic | monofocal |
| | B2AW00 S2AW00 | hydrophilic | monofocal |
| | B2AW00 S2AW00 | hydrophilic | monofocal |
| | 611HPS | hydrophilic | monofocal |
| Posterior chamber intraocular lens, pseudophakic, hydrophilic, blue light filter | B1EWYN S1EWYN | hydrophilic | trifocal |
| | B2EWYN S2EWYN | hydrophilic | trifocal |
| | B1TWYT S1TWYT S1TWY0 | hydrophilic | monofocal toric |
| | B1HWYN S1HWYN | hydrophilic | trifocal toric |
| | B1AWY0 S1AWY0 | hydrophilic | monofocal |
| | B2AWY0 S2AWY0 | hydrophilic | monofocal |

DEVICES INTENDED FOR USE TOGETHER WITH THE IOL

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

INTENDED PURPOSE

Hydrophilic posterior chamber IOLs are intended for implantation into the capsular bag in the posterior chamber of the eye to replace the human crystalline lens in adult patients to improve vision (either distance vision or distance, intermediate, near vision; and additionally, optionally reduce the cylindrical power of the eye).

MEDICAL INDICATION

MONOFOCAL MODELS

Hydrophilic posterior chamber monofocal IOLs are indicated for adults with cataract and/or ametropia (hyperopia, myopia), secondary to the removal of the crystalline lens.

TRIFOCAL MODELS

Hydrophilic posterior chamber trifocal IOLs are indicated for adults with cataract and/or ametropia (hyperopia, myopia) and/or presbyopia, secondary to the removal of the crystalline lens.

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MONOFOCAL TORIC MODELS

Hydrophilic posterior chamber monofocal toric IOLs are indicated for adults with cataract and/or ametropia (hyperopia, myopia, astigmatism), secondary to the removal of the crystalline lens.

TRIFOCAL TORIC MODELS

Hydrophilic posterior chamber trifocal toric IOLs are indicated for adults with cataract and/or ametropia (hyperopia, myopia, astigmatism) and/or presbyopia, secondary to the removal of the crystalline lens.

LIMITATIONS

There are no known limitations, except for age (18 years old and older).

PATIENT TARGET GROUP

Aphakic adult patients (18 years old and older).

INTENDED USERS

Hydrophilic IOLs must be handled and implanted by a qualified and skilled ophthalmic surgeon experienced in anterior segment surgery.

CLINICAL BENEFIT

The following clinical benefits are expected:

Hydrophilic posterior chamber monofocal IOLs are applicable to replace the human crystalline lens in adult patients, and to improve vision at far distance.

Hydrophilic posterior chamber trifocal IOLs are applicable to replace the human crystalline lens in adult patients, and to improve distance, intermediate and near vision.

Hydrophilic posterior chamber monofocal toric IOLs are applicable to replace the human crystalline lens in adult patients, to improve vision at far distance, and to reduce the cylindrical power of the eye.

Hydrophilic posterior chamber trifocal toric IOLs are applicable to replace the human crystalline lens in adult patients, to improve distance, intermediate and near vision, and to reduce the cylindrical power of the eye.

CONTRAINDICATIONS

Based on international guidelines, the contraindications of the IOL implantation:

Absolute contraindications:

- Surgery is not expected to improve visual function, and no other indication for lens removal exists.
- The patient cannot safely undergo surgery because of coexisting medical or ocular conditions.
- Appropriate postoperative care cannot be arranged.
- The patient or patient's surrogate decision maker is unable to give informed consent for nonemergent surgery.

Relative contraindication:

- Tolerable refractive correction provides vision that meets the patient's needs and desires.

The listed contraindications are to be considered for all 1stQ hydrophilic posterior chamber IOLs.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Summary of Safety and Clinical Performance (SSCP) may be requested at qm@1stq.de. 1stQ will send you the appropriate document without undue delay.

As soon as the European database on medical devices (EUDAMED) is fully functional, the Summary of Safety and Clinical Performance can be found on the EUDAMED public website linked to the following Basic UDI-DIs:

| Model | Basic UDI-DI |
|----------------------------|---|
| B1AW00 S1AW00 | 4057818B1AW00EP 4057818S1AW00ML |
| B1AWY0 S1AWY0 | 4057818B1AWY0JF 4057818S1AWY0RC |
| B2AW00 S2AW00 | 4057818B2AW00F2 4057818S2AW00MX |
| B2AWY0 S2AWY0 | 4057818B2AWY0JS 4057818S2AWY0RP |
| B1EWYN S1EWYN | 4057818B1EWYNM5 4057818S1EWYNU2 |
| B2EWYN S2AWYN | 4057818B2EWYNMG 057818S2EWYMUB |
| B1TWYT S1TWYT S1TWY0 | 4057818B1TWYTQS 4057818S1TWYTXP 4057818S1TWY0VH |
| B1HWYN S1HWYN | 4057818B1EWYNM5 4057818S1EWYNU2 |
| 611HPS | 4057818611HPS9M |

The URL of EUDAMED website: <https://ec.europa.eu/tools/eudamed>

WARNINGS AND PRECAUTIONS

Warnings and Precautions for use:

- Hydrophilic posterior chamber 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.
- 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.
- 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.
- 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.

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- 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.
- Intracameral use of the thrombolytic medication alteplase may lead to IOL opacification.
- In case of toric models, 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.
- In case of 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.
- In case of trifocal models, some patients may experience reduced contrast sensitivity as compared to monofocal IOLs.
- In case of trifocal models, 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.
- In case of trifocal models, patients should be advised that unexpected outcomes could lead to continued spectacle dependence.

Warnings and Precautions related to residual risks:

- IOL implantation is an invasive procedure; therefore, eye tissue damage, inflammation, or infection might occur occasionally.
- During the production, storage, shipment and handling, the product may be damaged. Damaged product cannot achieve the expected safety and performance requirements and therefore cannot be used for implantation.
- The IOL implantation is a complex procedure, and the manufacturer's supporting information provided with the device is needed to ensure proper implantation. If any information is missing, do not use the device.
- The implantation of an artificial IOL to replace the crystalline lens might change the exposure of the eye to external factors (e.g.: UV light, blue light etc.). Patients should be advised to wear UV protection spectacles in the sunlight to avoid damage by ultraviolet rays.
- The artificial material of the IOL may expose the patient to unintended, material-based risks (e.g.: glistening, material fatigue, opacification, leaching).
- Occasionally, under certain circumstances, the IOL may not meet the expected optical performance (e.g.: PCO, refractive error etc.). Patients should be advised that unexpected outcomes may necessitate additional surgical intervention.
- Due to the diversity and complexity of an IOL product, there may be a risk of implanting an improper model.

Warnings and Precautions about clinical conditions not investigated in clinical trials:

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:

- Corneal astigmatism > 1.5 D for monofocal, > 1.0 D for trifocal, < 1.0 D for toric IOLs

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- Uncontrolled diabetic retinopathy
- Iris neovascularization
- Congenital eye abnormality
- Uncontrolled glaucoma
- Pseudoexfoliation syndrome
- Amblyopia
- Uveitis
- AMD (advanced AMD)
- Retinal detachment
- Prior ocular surgery in personal medical history
- Previous laser treatment
- Corneal diseases
- Severe retinal diseases (dystrophy, degeneration)
- High myopia
- Inadequate visualization of the fundus on preoperative examination
- Patients deemed ineligible by the clinical investigator because of any systemic disease
- Pregnancy
- Eye trauma in medical history
- Current use of systemic steroids or topical ocular medication
- Operative complications of tear in capsulorhexis, zonular dehiscence, posterior capsular rupture vitreous loss and other unexpected surgical complication

In addition, for toric models:

- Irregular astigmatism

COMPLICATIONS

Based on current State of the Art, the following complications are known:

Intraoperative complications of cataract surgery

- Posterior capsular or zonular rupture
- Vitreous loss/anterior vitrectomy or aspiration
- Iris/ciliary body injury
- Loss of nuclear material into vitreous
- Suprachoroidal hemorrhage
- Retrobulbar hemorrhage
- Tissue damage, inflammation, or infection

Postoperative complications of cataract surgery

- Cystoid macular edema
- Iris abnormalities
- Corneal edema
- Wound leak or rupture
- IOL dislocation, removal, or exchange
- Endophthalmitis
- Retinal tear, break, or detachment

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- Persistent iritis
- TASS, TPSS
- Secondary glaucoma
- Ptosis
- Nicked epithelial membrane
- Light sensitivity
- Diplopia
- Blindness

Incidents related to IOLs under normal conditions of use (expected undesirable side-effects, common to all 1stQ hydrophilic posterior chamber IOLs)

- Posterior capsular opacification (PCO)
- Opacification and calcification
- Luxation
- Lens-related visual disturbances (dysphotopsias)
- IOL rotation
- Glistening

Incidents related to IOLs under conditions of misuse

- Incorrect IOL power, poor visual outcome
- Damaged IOL
- Decentration and dislocation
- Uveitis-glaucoma-hyphema syndrome

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. Prior to surgery mark the operative astigmatic 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 toric 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.

For trifocal lenses target emmetropia.

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

DIRECTIONS FOR USE

1. Examine the package labels carefully for information about the lens model, power and expiration date. 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).
2. Open the protective blister and remove the lens container from the packaging in a sterile environment. Hold the vessel vertically. Carefully open the cap and remove the lens holder from the fluid.
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. For optimal results, aim to achieve perfect IOL centration.
5. Hydrophilic IOLs should not be kept in open air for longer than 1 minute. The IOL should not be in folded condition for longer than 3 minutes. If these time limits have been exceeded the lens should be discarded.

DISPOSAL

The product or its waste material should be disposed of in accordance with local/national regulations and requirements.

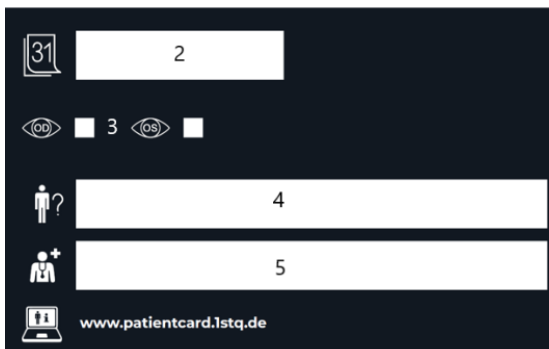
The waste from protective packaging, packaging inserts, sterile barrier system and lens container can be considered as non-hazardous municipal plastic waste (recommended European Waste Code: EWC200139).

The product waste that was in contact with the patient shall be considered as potentially infectious whose collection and disposal is subject to special requirements in order to prevent infection (recommended European Waste Code: EWC180103*).

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:



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www.patientcard.1stq.de



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MD

1stQ GmbH
Konrad-Zuse-Ring 23 · 68163 Mannheim, Germany
www.1stq.de











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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







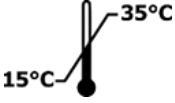




| | | | | | |
|---|--------------------------------------|---|----------------------------------|---|--|
|  | Patient Name or patient ID |  | Date of implantation |  | Name and Address of the implanting healthcare institution/provider |
|  | Name and Address of the manufacturer |  | Information website 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 |

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| | | |
|--|--|---|
|  Serial Number |  Use by date |  Caution |
|  Do not use if package is damaged |  Manufacturer |  Sterilized using steam or dry heat |
|  Temperature limit |  Date of manufacture |  Sterile barrier system with protective packaging inside |
|  Medical device |  Unique Device Identifier | |

PACKAGING

Hydrophilic lenses are supplied steam sterilized in a plastic vessel filled with sterile water. The containers are protected by blister.

STORAGE

Store the unopened IOL box in a dry place, away from moisture and direct sunlight at 15-35°C.

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.

MANUFACTURER

| | |
|---------------------|--|
| 1stQ GmbH | Tel: +49 621 7176330 |
| Konrad-Zuse-Ring 23 | Fax: +49 621 7176333 |
| 68163 Mannheim | www.1stq.eu |
| GERMANY | info@1stq.de |

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

LAST UPDATE:

March 2026

Revision number: 02

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

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