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## 1stQ E-IFU

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## BASIS IOL, HYDROPHOBIC IOL

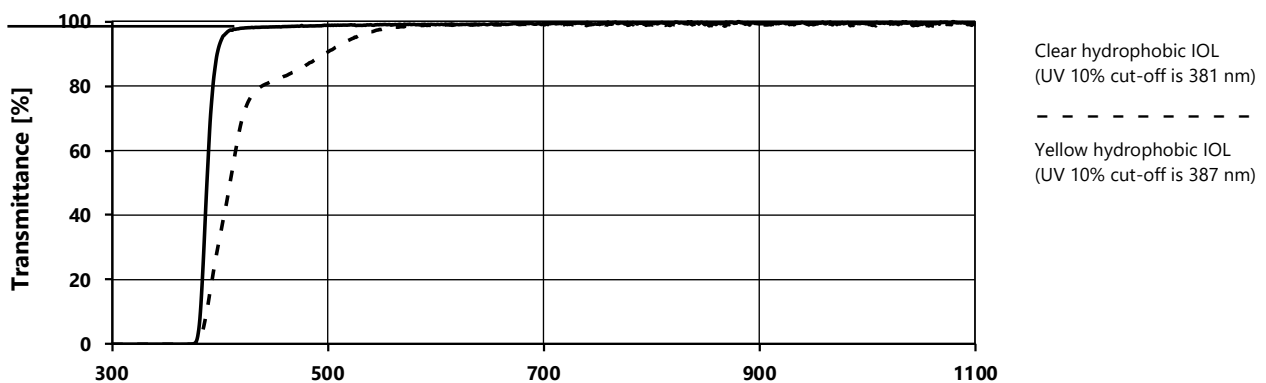
### INSTRUCTIONS FOR USE EN

#### DESCRIPTION

Single piece, sterile, foldable aspheric hydrophobic acrylic intraocular lenses (IOL) with UV blocker, optionally with blue light filter. The IOL material is 100% hydrophobic acrylic random copolymer based on ethyl acrylate and ethyl methacrylate, with covalently bound UV filter. 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. The optic can be monofocal or EDOF. The IOL is available as non-preloaded IOL, which must be manually loaded into an injector before implantation. Different models are controlled individually for their optical and mechanical properties.

EDOF (Extended Depth of Focus) models: EDOF lenses carry an additional optical function on the central portion of the anterior surface of the otherwise monofocal optic in order to create an extended focal range.

Graph 1: Average spectral transmittance of hydrophobic IOLs



#### MONOFOCAL MODELS

Model	Material	Design
877FAB	hydrophobic	monofocal
877FABY	hydrophobic	monofocal
B1AD00 S1AD00	hydrophobic	monofocal
B1ADY0 S1ADY0	hydrophobic	monofocal

#### EDOF MODELS

Model	Material	Design
877EBY	hydrophobic	EDOF

#### 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: [www.1stq.eu/compatibility](http://www.1stq.eu/compatibility). Devices other than those listed in the chart have not been tested and cannot be recommended.

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## STORAGE

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

## PACKAGING

Hydrophobic lenses are supplied dry, packaged in a plastic lens container, sterilized by ethylene oxide. The containers are protected by blister.

## 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 hydrophobic 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.

## MEDICAL INDICATION

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

Hydrophobic EDOF IOLs are indicated for adults with cataract and/or ametropia (hyperopia, myopia) and/or presbyopia, secondary to 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

1stQ hydrophobic 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:

Monofocal IOLs are applicable to replace the human crystalline lens in adult patients, and to improve distance vision.

EDOF IOLs are applicable to replace the human crystalline lens in adult patients, and to extend the depth of focus covering distance and intermediate vision.

## 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 contraindications:

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

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The listed contraindications are to be considered for all 1stQ hydrophobic IOLs.

## SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Summary of Safety and Clinical Performance (SSCP) may be requested at 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
877FAB	4057818877FABB2
877FABY	4057818877FABY7Z
B1AD00	4057818B1AD00BQ
S1AD00	4057818S1AD00JM
B1ADY0	4057818B1ADY0FG
S1ADY0	4057818S1ADY0ND
877EBY	4057818877EBYCE

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

## WARNINGS AND PRECAUTIONS

Warnings and precautions for use:

- Hydrophobic IOLs are designed to be implanted into the capsular bag only. There is no clinical data demonstrating the safety and efficacy of the implantation in the ciliary sulcus.
- Lenses should not be used after the expiration date.
- DO NOT resterilize or reuse the lenses 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.
- 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.
- Use of intraocular gas/air tamponade: Based on literature, deterioration in the transparency of the IOL has occasionally been observed upon the intraocular administration of SF6 or C3F8 gases. Visually significant haze may develop, potentially leading to an IOL exchange.

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 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.

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- The artificial material of the IOL may expose the patient to unintended, material-based risks (e.g.: glistening, material fatigue, opacification, leaching etc.)
- 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 IOLs, 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 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 > 1.5D for monofocal, > 0.75D for EDOF
- Uncontrolled diabetic retinopathy
- Iris neovascularization
- Serious intraoperative complications
- Congenital eye abnormality
- Uncontrolled glaucoma or glaucoma with changes in optical nerve and visual field
- Pseudoexfoliation syndrome
- Amblyopia
- Uveitis
- Long-term anti-inflammatory treatment
- AMD (advanced AMD)
- Retinal detachment
- Prior ocular surgery in personal medical history
- Corneal diseases
- Severe retinal diseases (dystrophy, degeneration)
- Severe myopia (if required IOL power is lower than 5 D)
- Inadequate visualization of the fundus on preoperative examination
- Patients deemed ineligible by the clinical investigator because of any systemic disease
- Eye trauma in medical history

## 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:

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

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### 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
- 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)

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

These side-effects are common to all 1stQ hydrophobic IOLs.

### 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.

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

## 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 labelling (e.g. power, model, SN).
2. Open the protective blister and remove the lens container from the packaging in a sterile environment. 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. For optimal results, aim to achieve perfect IOL centration.
5. The IOL should not be in folded condition for longer than 3 minutes. If this time limit has 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:



The image shows two views of a Patient Card form. The left view is a dark background with white text and icons. It includes a date field (2) with a calendar icon, an eye field (3) with eye icons, a surgeon field (4) with a person icon, and a surgeon ID field (5) with a person icon. The website www.patientcard.1stq.de is at the bottom. The right view shows a field (6) with a UDI 2D barcode, the MD logo, and the 1stQ GmbH logo and address: Konrad-Zuse-Ring 23 · 68163 Mannheim, Germany, www.1stq.de.

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).











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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		Caution
	Do not use if package is damaged		Manufacturer		Sterilized using ethylene oxide

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