



1stQ E-IFU

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BASIS IOL HYDROPHOBIC PRELOADED

INSTRUCTIONS FOR USE EN

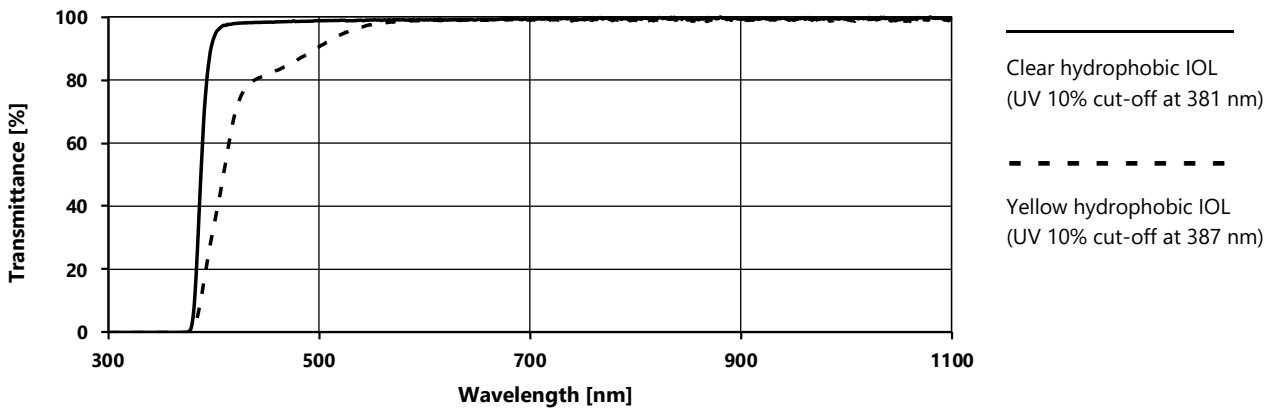
DESCRIPTION

Single piece, sterile, foldable 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 IOLs are available as part of a preloaded injector system. 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.

EDOF (Extended Depth of Focus) 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



MODELS

Model	Material	Design	Estimated corneal incision size
877PA	hydrophobic	monofocal	2.2 mm
877PAY	hydrophobic	monofocal	2.2 mm
B1AB00 S1AB00	hydrophobic	monofocal	2.2 mm
B1ABY0 S1ABY0	hydrophobic	monofocal	2.2 mm
877PT	hydrophobic	toric	2.2 mm
877PTY	hydrophobic	toric	2.2 mm
B1TB00 S1TB00	hydrophobic	toric	2.2 mm
B1TBY0 S1TBY0	hydrophobic	toric	2.2 mm
877PEY	hydrophobic	EDOF	2.2 mm
B1XBY0 S1XBY0	hydrophobic	EDOF	2.2 mm
877PETY	hydrophobic	EDOF 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.

STORAGE

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

EXPIRATION DATE

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

Preloaded 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

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

Preloaded hydrophobic monofocal toric IOLs are indicated for adults with cataract and/or ametropia (hyperopia, myopia, astigmatism), 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.

Preloaded hydrophobic EDOF toric IOLs are indicated for adults with cataract and/or ametropia (hyperopia, myopia, astigmatism), 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

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

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
877PA	4057818877PAJC
877PAY	4057818877PAYE2
877PT	4057818877PTKJ
877PTY	4057818877PTYFT
877PEY	4057818877PEYEE
877PETY	4057818877PETYCH
B1AB00 S1AB00	4057818B1AB00BE 4057818S1AB00JB
B1ABY0 S1ABY0	4057818B1ABY0F6 4057818S1ABY0N3
B1TB00 S1TB00	4057818B1TB00FK 4057818S1TB00NG
B1TBY0 S1TBY0	4057818B1TBY0KB 4057818S1TBY0S8
B1XBY0 S1XBY0	4057818B1XBY0L7 4057818S1XBY0T4
B1ZBY0 S1ZBY0	4057818B1ZBY0LM 4057818S1ZBY0TJ

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

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.

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

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 resterilise 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.
- 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.

Warnings and precautions for injection:

- 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 the 30-second waiting time, 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.
- 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.

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.
- 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 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 > 1.5D for monofocal, > 0.75D for EDOF, >1.0D for toric IOLs
- 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
- In addition, for toric models: irregular astigmatism

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

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, common to all preloaded hydrophobic 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
- 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 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 blister containing the injector system with the IOL and verify that the information on the blister is consistent with the outer package labelling (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).

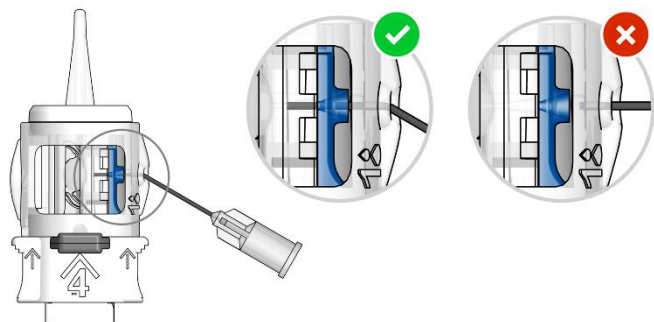


Fig. 1

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).

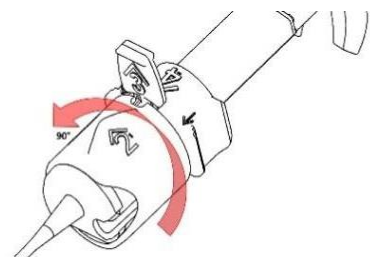


Fig. 2a

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

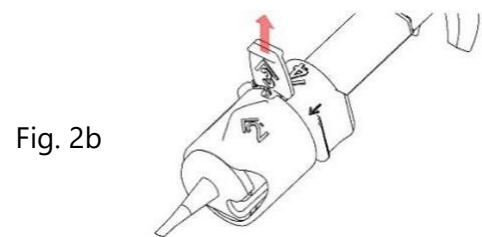


Fig. 2b

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

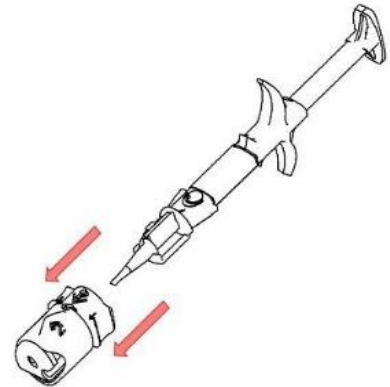


Fig. 3

- Push the plunger forward a few millimetres 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).

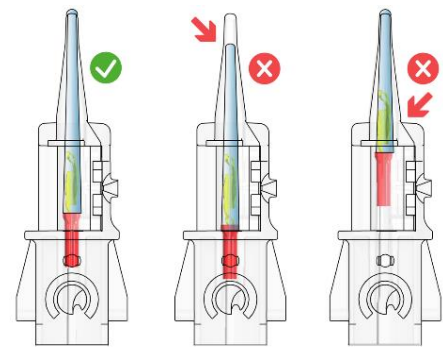


Fig. 4a

Fig. 4b

Fig. 4c

- Keep the injector in this state for 30 seconds.
- 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.
- Once the lens optic exits the cartridge tip, stop pressing and let the trailing haptic follow the optic.
- Carefully withdraw the cartridge nozzle from the eye once the injection process is completed.

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:




















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 manufacturer	 Caution
 Medical device	 Unique Device Identifier	

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Any adverse event that the lenses may have caused, any serious incident should be reported to 1stQ’s Quality Assurance at qm@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.