



1stQ E-IFU

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POSTERIOR CHAMBER INTRAOCULAR LENSES, PSEUDOPHAKIC, HYDROPHILIC For MEDJET PIL-MA or MEDICEL ACCUJECT (PRO) Single Use Injectors

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 IOL is preloaded, it is part of an injection system, delivered in a special lens holder, that must be inserted into a compatible injector before implantation. The two primary components of this preloaded injection system (the IOL and the injector) are packaged and sterilized separately.

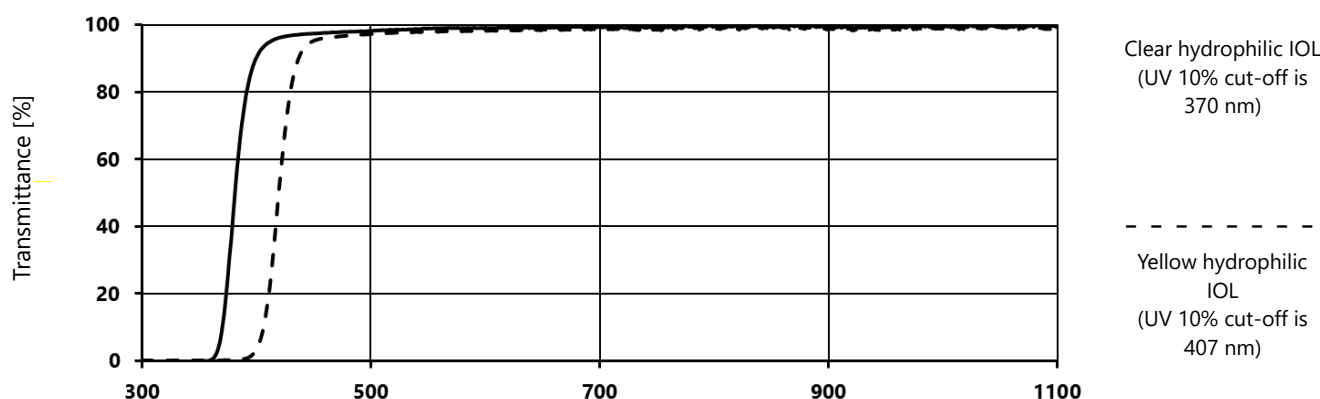
The optic can be monofocal, trifocal, monofocal toric or trifocal toric. Different models are controlled individually for their optical and mechanical properties.

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.

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

Graph 1: Average spectral transmittance of 1stQ hydrophilic IOLs



MODELS

Product name	Model	Material	Design
Posterior chamber intraocular lens, pseudophakic, hydrophilic	677P	hydrophilic	monofocal
	B2AP00	hydrophilic	monofocal
	B7EP0N S7EP0N	hydrophilic	trifocal
	B1EP0N S1EP0N	hydrophilic	trifocal
	677CTA	hydrophilic	monofocal toric
	B1TP0T S1TP0T	hydrophilic	monofocal toric
Posterior chamber intraocular lens, pseudophakic, hydrophilic, blue light filter	677PY	hydrophilic	monofocal
	B2APY0	hydrophilic	monofocal
	677PMY	hydrophilic	trifocal
	677CMY	hydrophilic	trifocal
	B1EPYN S1EPYN	hydrophilic	trifocal
	B2EPYN S2EPYN	hydrophilic	trifocal
	677CTAY	hydrophilic	monofocal toric
	B1TPYT S1TPYT S1TPY0	hydrophilic	monofocal toric
	677CMTY	hydrophilic	trifocal toric
	B1HPYN S1HPYN	hydrophilic	trifocal toric

DEVICES FOR USE IN COMBINATION

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. Products compatible with Medcel Accuject PRO injection system can be used with Medcel Accuject after removing the loading chamber from the injector.

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.

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 vision at far, intermediate and near distances.

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 vision at far, intermediate and near distances, and to reduce the cylindrical power of the eye.

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
677P	4057818677PT9
B2AP00	4057818B2AP00DX
B7EP0N	4057818B7EP0NJC
S7EP0N	4057818S7EP0NR9
B1EP0N	4057818B1EP0NGA
S1EP0N	4057818S1EP0NP7
677CTA	4057818677CTABG
B1TP0T	4057818B1TP0TKX
S1TP0T	4057818S1TP0TSU
677PY	4057818677PYK6
B2APY0	4057818B2APY0HP
677PMY	4057818677PMYEC
677CMY	4057818677CMYCB
B1EPYN	4057818B1EPYNL2
S1EPYN	4057818S1EPYNSX
B2EPYN	4057818B2EPYNLD
S2EPYN	4057818S2EPYNNTA
677CTAY	4057818677CTAY96
B1TPYT	4057818B1TPYTTP
S1TPYT	4057818S1TPYTWL
S1TPY0	4057818S1TPY0UE
677CMTY	4057818677CMTY9U
B1HPYN	4057818B1HPYNLP
S1HPYN	4057818S1HPYNLTL

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

CONTRAINDICATIONS

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

Absolute contraindications:

- Surgery is not expected to improve visual function;
- 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.

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.
- 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
- 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
- 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 implantation axis calculated by the toric formula(s).

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

DIRECTIONS FOR USE

1. Examine the package labels carefully for information about the lens model, power and expiration date.
2. 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).
3. Ensure that the appropriate, unexpired, sterile, and unused compatible MEDJET PIL-MA or Medical Accuject (PRO) injection system is available. See the compatibility matrix in the Devices for Use in Combination section for the list of compatible injectors.
4. Open the blister at the marked end and remove the lens container in a sterile environment.

5. Remove the peel-off aluminum foil from the wet lens container while holding the container horizontally.
6. For loading and injection of the lens, please refer to the Instructions for Use enclosed with the compatible MEDJET PIL-MA or Mediciel Accuject (PRO) injection system.
7. 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.

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:















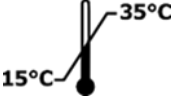


1. Place the label with UDI 2D barcode on the Implant card.
2. Fill in the date of implantation.
3. Mark the implanted eye - left (OS) or right (OD).
4. Fill in the name of patient or patient ID.
5. Fill in the name and address of the healthcare institution / provider.
6. Fill in the medical device name.



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	 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	
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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

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 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	www.1stq.de
	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.

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