



1stQ E-IFU

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ADDON INTRAOCULAR LENSES

INSTRUCTION FOR USE

EN

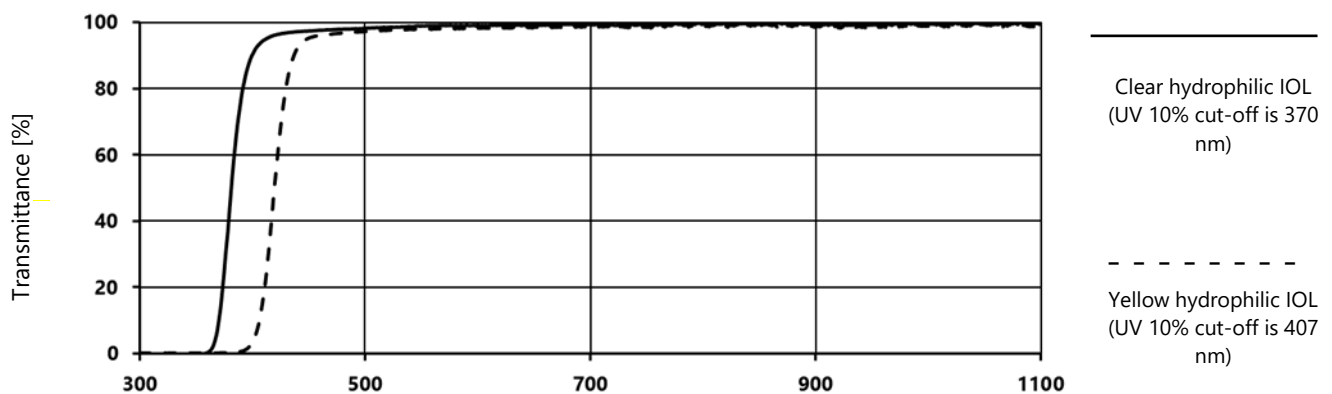
MODELS

Product name	Product	Material	Design
Posterior chamber intraocular lens, pseudophakic, hydrophilic, for implantation into the ciliary sulcus	A4SW00	Hydrophilic	multifocal
	A4MW00	Hydrophilic	bifocal
	A4TW0T A4TW00 A4FW0T A4FW00	Hydrophilic	monofocal toric
	A4HW0M	Hydrophilic	trifocal toric
	A4EW0M A4DW0M	Hydrophilic	trifocal
	A4EW0H A4DW0H A4DW0K	Hydrophilic	EDOF

DESCRIPTION

AddOn posterior chamber intraocular lenses are single piece, sterile, foldable, hydrophilic acrylic, **aspheric**, optical devices with UV-blocker. The optic can be monofocal, bifocal, trifocal, EDOF, monofocal toric or trifocal toric. The IOL is non-preloaded and must be manually loaded into a compatible injector.

Graph 1: Average spectral transmittance of 1stQ IOLs



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DEVICES INTENDED FOR USE TOGETHER WITH THE IOL

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

INTENDED PURPOSE

Addon posterior chamber intraocular lenses are intended for implantation into the ciliary sulcus in the posterior chamber of pseudophakic patients to improve vision.

MEDICAL INDICATION

AddOn monofocal IOL is indicated for pseudophakic adults with residual refractive error (hyperopia, myopia).

AddOn bifocal IOL indicated for pseudophakic adults with a dry form of age-related macular degeneration.

AddOn trifocal IOLs are indicated for pseudophakic adults with residual refractive error (hyperopia, myopia) and/or presbyopia.

AddOn EDOF IOLs are indicated for pseudophakic adults with residual refractive error (hyperopia, myopia) and/or presbyopia.

AddOn monofocal toric IOLs are indicated for pseudophakic adults with residual refractive error (hyperopia, myopia, astigmatism).

LIMITATIONS

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

PATIENT TARGET GROUP

Adult patients (18 years old or older).

INTENDED USERS

Addon Intraocular lenses must be handled and implanted by a qualified and skilled ophthalmic surgeon experienced in anterior segment surgery.

CLINICAL BENEFIT

In terms of performance and safety, the following clinical benefit claims are expected to be justified by clinical data of AddOn IOLs:

Monofocal AddOn IOLs are applicable to improve distance vision in pseudophakic adults with residual refractive error (hyperopia, myopia).

Bifocal AddOn IOLs are applicable to improve near vision in pseudophakic adults with a dry form of age-related macular degeneration.

Trifocal AddOn IOLs are applicable to improve intermediate and near vision and optionally to provide refractive adjustment in pseudophakic adults with residual refractive error (hyperopia, myopia) and/or presbyopia.

EDOF AddOn IOLs are applicable to improve intermediate vision and optionally to provide refractive adjustment in pseudophakic adults with residual refractive error (hyperopia, myopia) and/or presbyopia.

Monofocal toric AddOn IOLs are applicable to reduce the cylindrical power of the eye and optionally to provide refractive adjustment in pseudophakic adults with residual refractive error (hyperopia, myopia, astigmatism).

Trifocal toric AddOn IOLs are applicable to reduce the cylindrical power of the eye, to improve intermediate and near vision and optionally to provide refractive adjustment in pseudophakic adults with residual refractive error (hyperopia, myopia, astigmatism) and/or presbyopia.

Clinical data are expected to demonstrate that, in terms of safety and performance the use of the 1stQ AddOn IOLs is safe, the performance meets the expected values based on the state of the art.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Summary of Safety and Clinical Performance (SSCP) may be requested at qm@1stq.de. 1stQ GmbH 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
A4SW00	4057818A4SW00K9
A4DW0K	4057818A4DW0KHL
A4DW0M A4EW0M	4057818A4DW0MHQ 4057818A4EW0MHX
A4DW0H A4EW0H	4057818A4DW0HHE 4057818A4EW0HHM
A4TW0T A4TW00 A4FW0T A4FW00	4057818A4TW0TMN 4057818A4TW00KG 4057818A4FW0TJL 4057818A4FW00GE
A4HW0M	4057818A4HW0MJL
A4MW00	4057818A4MW00HX

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

CONTRAINDICATIONS

Based on international guidelines, the **non-specific 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.

Specific contraindications of AddOn IOLS:

Absolute contraindications:

- Loose zonules from trauma or pseudoexfoliation;
- The presence of posterior synechiae to the capsular bag.

Relative contraindications:

- Preoperative presence of pigmentary dispersion syndrome, especially in the presence of glaucoma or elevated IOP;
- Capsular tension ring was required for primary lens implantation.

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

WARNINGS AND PRECAUTIONS

Warnings and Precautions for use:

- Addon IOLs are designed to be implanted into the ciliary sulcus in the posterior chamber. There is no clinical data demonstrating the safety and efficacy of an implantation in the capsular bag.
- 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.
- 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 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.

- In case of toric models, Carefully remove all viscoelastic material from both sides of the lens. Residual viscoelastic material may cause complications including increase of intraocular pressure.
- Intracameral use of the thrombolytic medication alteplase may lead to IOL opacification.
- Shallow ACD (< 2.8 mm; pseudophakic; from endothel) and narrow angle (i.e., < Schaffer grade 2) increase the risk of complications from sulcus IOL implantation.

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.

TRIFOCAL MODELS

- The implantation of diffractive sulcus IOL models is not recommended in addition to a diffractive primary IOL.
- Manage patient selection and operative technique carefully to ensure that the total postoperative corneal astigmatism does not exceed 0.75 diopters.
- Only patients with fully functional pupil should be implanted.
- Some patients may experience reduced contrast sensitivity as compared to monofocal IOLs.
- Some patients may experience visual effects with 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.

BIFOCAL MODELS

- For the A45SML model, patients should be considered suitable for implantation where an improvement of at least 1 line (0.1 logMAR) could be observed between the results of the visual testing of T6.0, compared to T2.5.

Warnings and Precautions related to residual risks:

- IOL implantation is an invasive procedure; therefore, eye tissue damage, inflammation, or infection might occur occasionally.
- During production, storage, shipment and handling, the product may be damaged. Damaged products 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 could lead to continued spectacle dependence or 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 investigations:

The safety and effectiveness of AddOn IOLs have not been studied in patients with certain existing conditions and /or intraoperative complications listed below (as these patients were excluded from clinical investigations). Careful preoperative and perioperative evaluation and clinical judgement should be made by the ophthalmic surgeon to decide the risk/benefit ratio before implantation in the following (non-exhaustive) pre-existing conditions:

- Anterior chamber depth (ACD) less than 2.8 mm;
- Subjects with monocular corrected distance visual acuity (CDVA) worse than LogMAR=0.1;
- Pregnancy;
- Narrow angle, i.e., < Schaefer grade 2;
- Severe zonulopathy;
- Uveitis, iris atrophy, advanced glaucoma with significant visual field defect, pigment;
- dispersion syndrome;
- Active neovascular AMD;
- Status after complicated surgery, congenital eye abnormality;
- Amblyopia;
- Pupillary abnormality.

COMPLICATIONS

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
- Blepharitis/meibomianitis
- Posterior capsular striae/wrinkles
- Dry eye/SPK/epithelial erosion/tear film insufficiency
- Conjunctival hyperaemia
- TASS, TPSS
- Secondary glaucoma
- Ptosis
- Nicked epithelial membrane
- Light sensitivity
- Diplopia
- Blindness

Incidents related to sulcus IOLs under normal conditions of use (expected side-effects)

- Chronic IOP elevation
- Dysphotopsia
- Pigment dispersion syndrome
- Pigment deposits on the IOL
- Cell deposits (macrophages) on the IOL
- IOL rotation
- Fibrin deposits
- Pupillary capture
- Interlenticular opacification

Additionally, the following side-effects may also be relevant for the model indicated in AMD, based on published side-effects of implantable vision-enhancing devices used in advanced AMD:

- Glare (causing visual discomfort and impaired vision);
- Shadowing of images (unclear or shadowed vision);
- Diplopia for distance vision (double vision when viewing distant objects);
- Narrow field of view (limited peripheral vision);
- Anterior vaulting of the IOL (potentially leading to visual disturbances);
- Pupillary block (possibly causing increased IOP and visual disturbances);
- Explantation because of patient dissatisfaction
- Sunset syndrome (reduced visual acuity in low light, potentially requiring vitrectomy);
- Blurred vision (difficulty in seeing fine details clearly).

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 peel-pouch or 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 peel-pouch or 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. The IOL is implanted into the ciliary sulcus using an injector. 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. Unlike capsular bag implanted lenses, this 1stQ AddOn Intraocular lens must be folded in the opposite direction. Position the lens in the loading bay of the cartridge with the haptics positioned securely under the edge of the two grooves of the cartridge in a "reverse-U" (n) configuration. This ensures that the lens is folded and bent with the haptics pointing down. This way the lens will unfold with the leading haptics downwards into the ciliary sulcus.

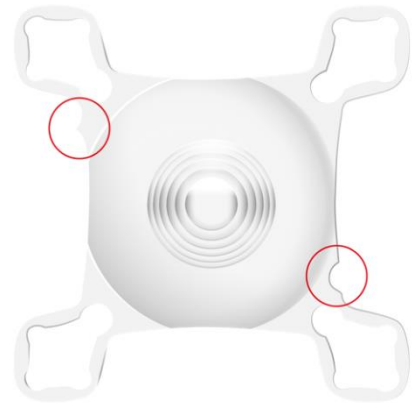


Figure 1.

5. 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.

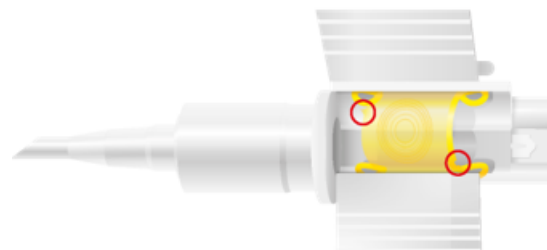


Figure 2.

6. Hydrophilic IOL should not be kept in open air for longer than 1 minute. The IOL should not be in a folded condition for longer than 3 minutes. If these time limits have been exceeded, the lens should be discarded.

PREOPERATIVE CALCULATION OF IOL POWER

IOL power should be determined preoperatively based on proper biometry data using the formulae available in literature. It is advised that surgeons personalize their calculation based on their surgical techniques, equipment and post-operative results. For 1stQ AddOn Intraocular lenses the use of a computerized/web-based Addon IOL calculator is highly recommended to ensure the best optical outcome. For further information please refer to:

<https://www.1stq.de/en/34-addoncalculator> or <http://www.1stq.de>

For diffractive trifocal lenses target emmetropia.

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.

DISPOSAL

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

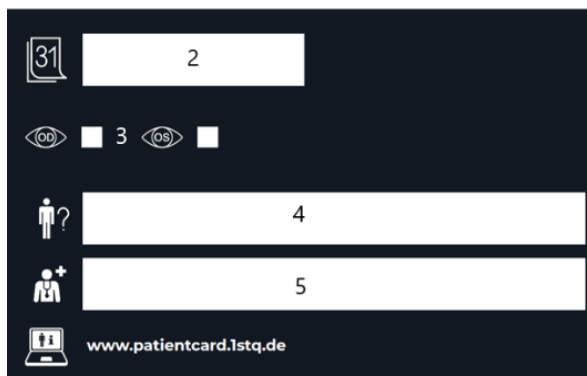
The waste from protective packaging, package inserts, sterile barrier system, and lens container can be considered as non-hazardous municipal plastic waste (recommended European Waste Code: EWC200139).

The product waste that was in contact with the patients shall be considered as potentially infectious, whose collection and disposal is subject to special requirements 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 must be filled in by the healthcare facility / healthcare provider as follows:



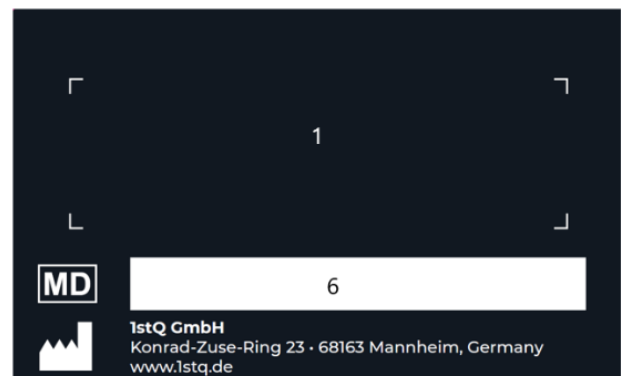
31 [] 2

OD [] 3 OS []

[]? [] 4

[]+ [] 5

www.patientcard.1stq.de



[] 1 []

[] []











MD [] 6

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













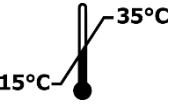




1. Place the label with UDI 2D barcode on the Implant card.
2. Fill in the date of implantation
3. Mark the implanted eye - left (OS) or right (OD).
4. Fill in the name of patient or patient ID.
5. Fill in the name and address of the healthcare institution / provider.
6. Fill in the device name.

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
 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 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 events 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: **May 2026** Revision number: **02**

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