



MEDICONTUR E-IFU

Confidentiality Statement

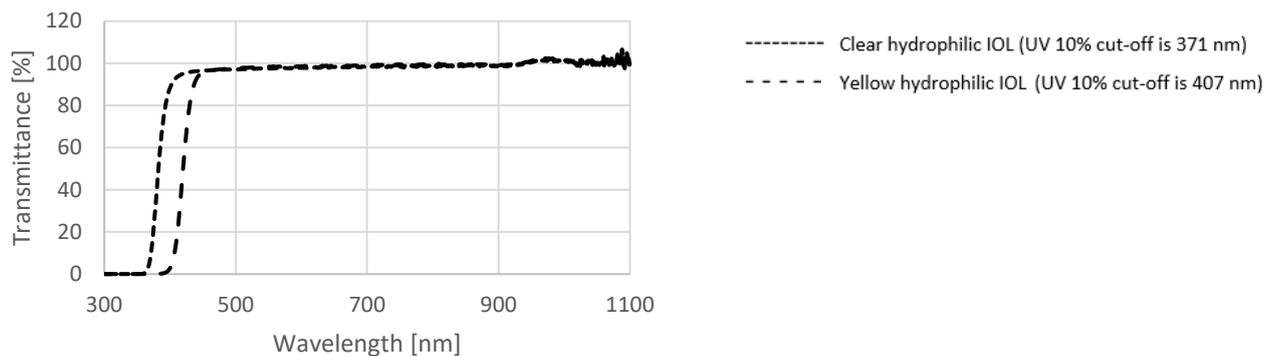
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MEDICONTUR HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INSTRUCTIONS FOR USE EN

DESCRIPTION

Consists of one, single piece, sterile, foldable acrylic intraocular lens (IOL) with UV-absorbent. 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. Different models are controlled individually for their optical and mechanical properties.

Graph 1: Average spectral transmittance of Medicontur IOLs



Code	Material	Design
611HPS	hydrophilic	monofocal
18ALY	hydrophilic	monofocal

PACKAGING

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

EXPIRATION DATE

Medicontur IOLs are sterile unless their primary packaging is damaged. The expiry date is printed on the labels of the outer packaging and the protective blister or peel-pouch. Do not use an IOL after its expiry date.

INTENDED USE

Optical implant intended to be positioned in the posterior chamber of the eye, for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients.

PRECAUTIONS

Careful preoperative evaluation and clinical judgement should be made by the surgeon to decide the risk/benefit ratio of the implantation in the following (non-exhaustive) pre-existing conditions:

- Choroidal hemorrhage
- Significant vitreous loss
- Extremely shallow anterior chamber
- Posterior capsular rupture
- Severe corneal dystrophy
- Severe optic nerve atrophy
- Zonular separation
- Color vision deficiencies
- Uncontrolled glaucoma
- Chronic uveitis
- Diabetic retinopathy

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- Retinal detachment
- Recurrent anterior or posterior segment inflammation of unknown etiology
- Clinically significant macular/RPE changes

CONTRAINDICATIONS

There are no known contraindications for the use of acrylic hydrophilic IOLs during the implantation.

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:

- Corneal damage or edema
- Cystoid macular edema
- Secondary glaucoma
- Pupillary block
- Uveitis
- Iris trauma
- Intraocular infection
- IOL replacement or extraction
- Hemorrhage
- Damage to the zonules or to the capsule with consequential IOL dislocation
- Posterior capsule opacification (PCO)
- Postoperative opacification/calcification of the IOL
- Endophthalmitis
- Asthenopic discomfort, adaption difficulties
- Reduced contrast sensitivity
- Reduced vision at night or in poor visibility conditions
- Perception of halos or radial lines around point sources of light
- Dissatisfactory visual outcome due to incorrect IOL refraction

WARNINGS

- Examine the package labels carefully for information about the lens model, power and expiration date. 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.
- Store the unopened IOL box in a dry place, away from moisture and direct sunlight at 15-35°C.
- 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.
- A high level of surgical skills is required to implant intraocular lenses. The surgeon should have observed and/or assisted at numerous implantations and successfully completed one or more courses on IOL implantation before attempting to implant intraocular lenses.
- 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.
- Patients should be advised that unexpected outcomes may necessitate additional surgical intervention.

- For optimal results, aim to achieve perfect IOL centration.
- The product or its waste material should be disposed of in accordance with local/national regulations and requirements.
- 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.

LIABILITY

Medicontur 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 formulae 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.

DIRECTIONS FOR USE

1. 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.
 - Hydrophilic lenses: Hold the vial or 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.
5. Hydrophilic IOLs should not be kept in open air for longer than 1 minute. Neither type of IOL should be in folded condition for longer than 3 minutes. If these time limits have been exceeded the lens should be discarded.

PATIENT CARD

One of the self-adhesive labels with the IOL data printed on it is designed to be placed on the Patient 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.

SYMBOLS

 <p>CE certified</p>	 <p>Keep dry</p>	 <p>Do not re-use</p>
 <p>Keep away from sunlight</p>	 <p>Consult instructions for use</p>	 <p>Do not resterilize</p>
 <p>Serial number</p>	 <p>Use by date</p>	 <p>Temperature limit 15 °C - 35 °C</p>

 <p>Do not use if package is damaged</p>	 <p>Manufacturer</p>	 <p>Do not freeze</p>
 <p>Sterilized using steam or dry heat</p>		

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Please report any adverse event or complaint to Medicontur’s Quality Assurance at QA@medicontur.hu.

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