MEDICONTUR E-IFU

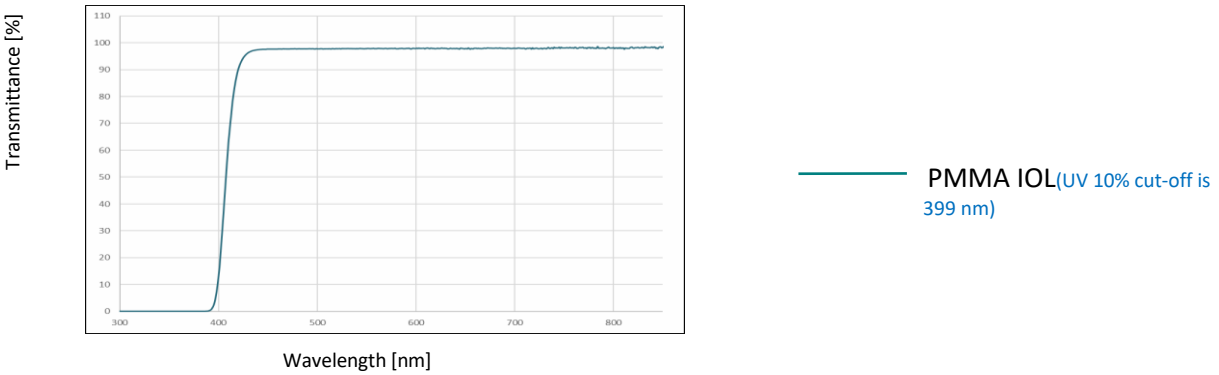
MEDICONTUR PMMA INTRAOCULAR LENSES EN

DESCRIPTION

Consists of one, single piece, sterile, unfoldable poly(methylmetacrylate) (PMMA) lens (IOL) with UV- absorbent (see Graph 1). On the haptics of several PMMA lenses there are holes to ease scleral fixation. Different models are controlled individually for their optical and mechanical properties.

Graph 1:

Average spectral transmittance of Medicontur PMMA IOLs



PMMA IOL for the capsular bag

Code	Material	Design
601MP	PMMA	monofocal
653MP	PMMA	monofocal
700MP	PMMA	monofocal

PMMA IOL for the anterior chamber

Code	Material	Design
91A	PMMA	monofocal

PACKAGING

PMMA lenses are supplied dry, packaged in a plastic lens case, sterilized by ethylene oxide. The lens cases 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. Do not use an IOL after its expiry date.

INDICATIONS

Correction of aphakia after surgical cataract extraction in adult patients. Medicontur "PMMA" IOLs are intended for replacement of the human crystalline lens in the capsular bag, in the posterior chamber of the eye.

PMMA lens 91A - an angle-supported monofocal intraocular lens to be implanted into the anterior chamber of the eye of adults after the removal of a cataractous lens by extracapsular cataract extraction including phacoemulsification. To be applied only if the implantation of an otherwise properly selected intraocular lens is not possible into the capsular bag.

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

CONTRAINDICATIONS

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list must be respected:

CONTRAINDICATIONS -PMMA IOL for the capsular bag

In case of patients who underwent previous refractive treatment – for example any kind of keratoplasty – the indication should be determined very carefully.

CONTRAINDICATIONS - PMMA IOL for the anterior chamber

- implantation into a phakic eye
- age ≤ 21 years
- iridocorneal angle under 30°
- corneal endothelial cell count (cECC) below 2300 cells/mm2, (below 2000/mm2 , if the patient is older, than 40 years)
- any anomaly of the iris or pupil function
- mesopic pupil size ≥ 5.0-6.0 mm
- intraocular pressure above 21 mmHg or know glaucoma disease
- active disease in the anterior segment of the eye
- recurrent or chronic uveitis
- “true” ACD (from corneal endothelial surface to the anterior surface of the lens) below average value (≤2.5 mm)

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, adaptional 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 room temperature (15-35°C).
- 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.

WARNINGS - PMMA IOL for the anterior chamber

- The patients' regular follow-up is especially important after the implantation of the anterior chamber lens 91A which includes the monitoring of the changes in the intraocular pressure and corneal endothelial cell count.

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 blister or pouch pack and verify that the IOL container information is consistent with the outer package labeling (e.g. power, model, SN).
2. Open the protective blister or pouch and remove the lens container from the packaging in a sterile environment.
3. Open and remove the container cap to expose the lens.
4. Thoroughly rinse the lens with a sterile intraocular irrigating solution (BSS) before the implantation.
5. Various surgical procedures can be utilized. The surgeon should select a technique that is appropriate for the patient.

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

CE 0120 CE certified	Keep dry	Do not re-use
Keep away from sunlight	Consult instructions for use	Do not resterilize
SN Serial number	Use by date	STORE AT ROOM TEMPERATURE Store at room temperature
Do not use if package is damaged	Manufacturer	DO NOT FREEZE! Do not freeze
STERILE EO Sterilized using ethylene oxide		

MANUFACTURER

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

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