MEDICONTUR E-IFU

MEDICONTUR SUPPLEMENTARY (ADDON) INTRAOCULAR LENSES

EN

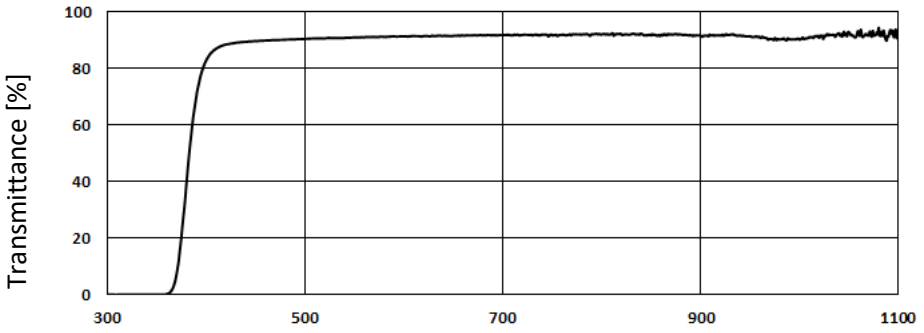
MODELS

Code	Design
A46R	Monofocal refractive
A45RD2	Multifocal diffractive
A45RT	Monofocal refractive toric
A45DT	Multifocal diffractive toric
A45SML	Multifocal refractive

DESCRIPTION

Medicontur supplementary (AddOn) intraocular lenses are single piece, sterile, foldable, hydrophilic acrylic optical devices with UV-absorbent. Different models are controlled individually for their optical and mechanical properties.

Graph 1: Average spectral transmittance of Medicontur IOLs



Clear hydrophilic IOL (UV 10% cut-off is 371 nm)

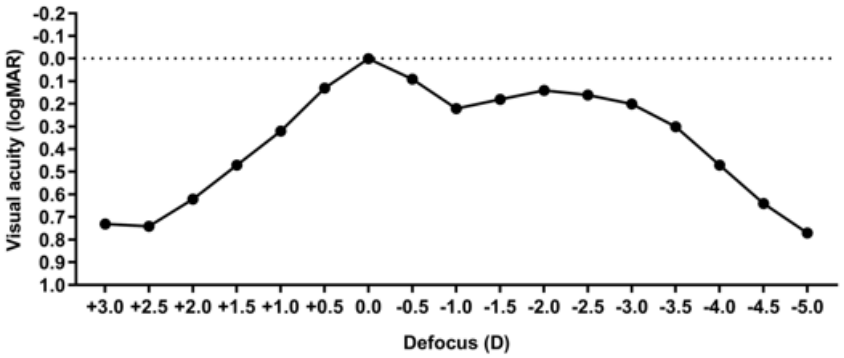
EXTENDEND DESCRIPTION TORIC MODELS

In case of monotoric lenses the toric surface is on the anterior side, whereas in case of bitoric lenses both sides are toric.

EXTENDEND DESCRIPTION MULTIFOCAL DIFFRACTIVE MODELS

The anterior surface is the diffractive side of the lens. The added power for near vision is indicated on the label. Defocus curves are shown in Graph 2.

Graph 2: Average defocus curves at 3.0mm pupil size for models A45RD2 and A45DT (with +3.0 D Add)



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

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

Medicontur supplementary (Addon) IOLs are intended for implantation into the ciliary sulcus of pseudophakic patients with a primary intraocular lens implanted in the capsular bag.

EXTENDED INDICATIONS – A46R

- A46R is intended to provide refractive adjustment to the pseudophakic eye.

EXTENDED INDICATIONS – A45RD2

- A45RD2 is intended to provide additional near and intermediate vision with increased spectacle independence and adjustment to the dioptric power for pseudophakic patients.

EXTENDED INDICATIONS – A45RT

- A45RT is intended to provide refractive adjustment and to correct for refractive errors caused by astigmatism in the pseudophakic eye.

EXTENDED INDICATIONS – A45DT

- A45DT is intended to provide improved near vision with increased spectacle independence and to correct for refractive errors caused by astigmatism in the pseudophakic eye.

EXTENDED INDICATIONS – A45SML

- A45SML is intended to provide improved near vision of pseudophakic patients with the dry form of age-related macular degeneration.

CONTRAINDICATIONS

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

- Aphakia
- Microphthalmia
- Shallow anterior chamber (< 2.8 mm)
- Narrow angle, i.e. < Schaefer grade 2

- Congenital eye abnormality
- Pigment dispersion syndrome
- Pseudophakic patients with malpositioned, subluxated or unstable capsular fixated intraocular lens
- Inability to achieve secure placement in the designated location e.g. due to absence of a secure peripheral anterior capsule, absence of intact zonules, or irregular anatomy of the ciliary sulcus
- Active ocular diseases (chronic severe uveitis, proliferative diabetic retinopathy, chronic glaucoma not responsive to medication, iris atrophy, severe zonulopathy)
- Children and adolescents under the age of 18 years
- Corneal decompensation

EXTENDED CONTRAINDICATIONS – A45RD2, A45DT

- Patients with a multifocal capsular bag fixated IOL
- Unstable Keratoconus, irregular astigmatism
- Age-related Macular Degeneration and other progressive retinal degenerations
- Any eye disease in which postoperative visual acuity is not expected to be better than 0.5 (e.g. amblyopia, nystagmus, retinitis pigmentosa, aniridia, eccentric pupil)
- Pathological pupil reactions

EXTENDED CONTRAINDICATIONS – A45SML

- Active neovascular (wet) age-related macular degeneration
- Iris neovascularization
- Inadequate visualization of the fundus on preoperative examination
- Preoperative ineffective miotic pupillary reaction or non-mydriatic pupil size or more than 4 mm under photopic conditions

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 exchange or extraction
- Hemorrhage
- 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).
- 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.
- Do not implant the supplementary (AddOn) IOL into the capsular bag.
- 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 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.
- Carefully remove all viscoelastic material from both sides of the lens. Residual viscoelastic material may cause complications including increase of intraocular pressure.
- Patients with chronic autoimmune diseases under long term treatment should be considered as risk patients since exacerbation of their condition might occur.

EXTENDED WARNINGS TORIC MODELS

- Prior to surgery mark the operative eye with at least two reference points 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 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 post-incision steep corneal meridian.
- 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.

EXTENDED WARNINGS MULTIFOCAL DIFFRACTIVE MODELS

- 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 the multifocal 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.
- Patients should be advised that unexpected outcomes could lead to continued spectacle dependence.

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. It is advised that surgeons personalize their calculation based on their surgical techniques, equipment and post-operative results. For supplementary (AddOn) IOLs 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.medicontur.com.

For diffractive multifocal lenses target emmetropia.

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. 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. Unlike capsular bag implanted lenses, this Supplementary (AddOn) IOL has to be folded in the opposite direction. Position the lens in the loading bay of the cartridge with he haptics positioned securely under the edge of the two grooves of the cartridge in a "reverse-U" (∩) 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.
5. Various surgical procedures can be utilized. The surgeon should select a technique that is appropriate for the patient.
6. Hydrophilic IOLs should not be kept in open air for longer than 1 minute.

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	STERILIZE	Do not re-sterilize
SN	Serial Number		Use by date	STERILE	Sterilized using steam or dry heat
	Do not use if package is damaged		Manufacturer	35°C 15°C	Store between 15°C - 35°C

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.