MEDICONTUR E-IFU

MEDICONTUR SUPPLEMENTARY (ADDON) INTRAOCULAR LENSES
INSTRUCTIONS FOR USE EN

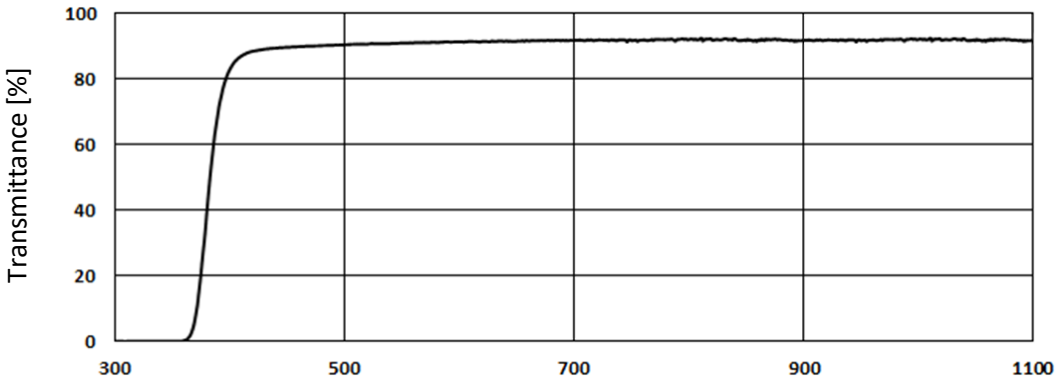
MODELS

Code	Design
A46R	Monofocal refractive
A45RD2	Trifocal diffractive
A45RT	Monofocal refractive toric
A45DT	Trifocal diffractive toric
A45SML	Multifocal refractive
A4EDF1	EDOF diffractive
A4EDF2	EDOF diffractive

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 at 371 nm)

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.

DIFFRACTIVE MODELS

The anterior surface is the diffractive side of the lens. The added power for near vision is indicated on the label.

DEVICES INTENDED FOR USE TOGETHER WITH THE IOL

The IOL should be implanted with a suitable injector. A compatibility chart can be found on our website: www.medicontur.com/professionals/compatibility. Devices other than those listed in the chart have not been tested and cannot be recommended.

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 PURPOSE

MEDICONTUR Supplementary (Addon) IOLs are posterior chamber intraocular lenses intended for implantation into the ciliary sulcus in the posterior chamber of pseudophakic patients with a primary intraocular lens implanted in the capsular bag.

MEDICAL INDICATION

MONOFOCAL MODEL

A46R is indicated for pseudophakic patients with a primary IOL in the capsular bag who aspire to have a refractive adjustment

DIFFRACTIVE MODELS

A45RD2 is indicated for pseudophakic patients with a primary IOL in the capsular bag who aspire to have additional near and intermediate vision with increased spectacle independence and optionally a refractive adjustment.

A4EDF1, A4EDF2 are indicated for pseudophakic patients with a primary IOL in the capsular bag who aspire to have additional intermediate with increased spectacle independence and optionally a refractive adjustment.

MONOFOCAL-TORIC MODEL

A45RT is indicated for pseudophakic patients with a primary IOL in the capsular bag who aspire to have a correction of their corneal astigmatism and optionally a refractive adjustment.

DIFFRACTIVE-TORIC MODEL

A45DT is indicated for pseudophakic patients with a primary IOL in the capsular bag who aspire to have improved near and intermediate vision with increased spectacle independence including a correction of corneal astigmatism and optionally refractive adjustment.

SCHARIOTH MACULA LENS MODEL

A45SML is indicated for pseudophakic patients with a dry form of age-related macular degeneration having a primary IOL in the capsular bag who aspire to have improved near vision.

CONTRAINDICATIONS

There are no known contraindications to the use of Medicontur Posterior Chamber IOL when used as recommended.

PATIENT TARGET GROUP

Pseudophakic adult patients (18 years old and older) with a primary capsular bag fixated intraocular lens.

INTENDED USERS

Medicontur supplementary (Addon) IOLs must be handled and implanted by a qualified and properly trained ophthalmic surgeon.

PRECAUTIONS

The safety and effectiveness of Medicontur 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:

- 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)
- Iris neovascularization
- Inadequate visualization of the fundus on preoperative examination
- Bacterial or viral endophthalmitis
- Choroidal hemorrhage
- Retinal detachment
- Pseudoexfoliative syndrome
- Corneal decompensation
- Irregular astigmatism
- Age-related Macular Degeneration and other progressive retinal degenerations
- Pathological pupil reactions

- Preoperative ineffective miotic pupillary reaction or non-mydriatic pupil size of more than 2.5 mm under photopic conditions
- Severe corneal dystrophy
- Diabetic retinopathy
- Clinically significant macular or Retinal Pigment Epithelium changes
- Previous retinal detachment
- Pregnancy

DIFFRACTIVE MODELS
- Patients with a multifocal primary IOL in the capsular bag
- Keratoconus
- 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)
- Monocular patients
- Individuals who drive at night for a living or whose occupation or hobbies depend on good night vision
- Individuals who need good near vision in semidarkness

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

SCHARIOTH MACULA LENS MODEL
- Active neovascular (wet) age-related macular degeneration

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:

Disease related complications
- Corneal damage or edema
- Secondary glaucoma

Preoperative
- Pupillary block
- Iris trauma
- Hemorrhage

Postoperative
- Intraocular infection
- IOL exchange or extraction
- Uveitis
- Cystoid macular edema
- Postoperative opacification/calcification of the IOL
- TASS, Endophthalmitis
- Asthenopic discomfort, adaptational difficulties
- Reduced contrast sensitivity

- Perception of halos or radial lines around point sources of light
- Dissatisfactory visual outcome due to incorrect IOL refraction
- Reduced vision at night or in poor visibility conditions
- Acceleration of the preexisting Macular degeneration leading to blindness.

WARNINGS

- Medicontur supplementary (Addon) IOLs are designed to be implanted into the ciliary sulcus in the posterior chamber. There is no sufficient clinical data demonstrating the safety and efficacy of an implantation in the capsular bag.
- 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.
- DO NOT USE the product if the package was unintentionally opened before use.
- 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 ophthalmic 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.
- Patient should be advised to wear spectacles in the sunlight to avoid damage by UV light.
- 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.

TORIC MODELS

- Prior to surgery mark the operative eye with at least two reference points (patient in 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 ciliary sulcus. 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.

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

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 the 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.

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 trifocal lenses target emmetropia.

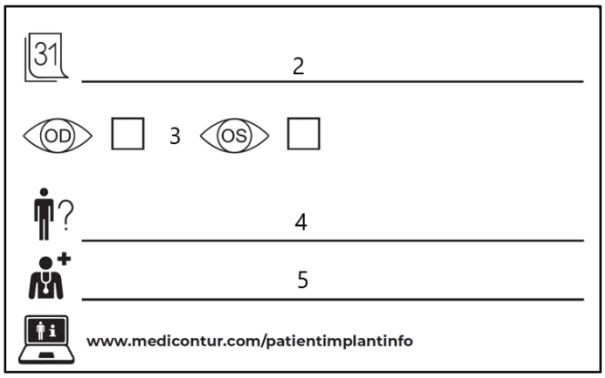
LIABILITY

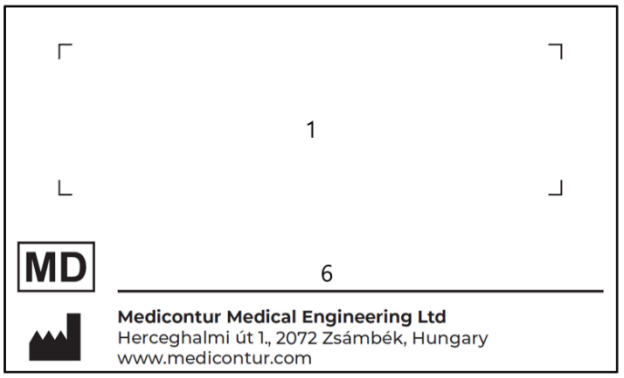
Medicontur does not bear any responsibility for improper model selection by the physician, for improper handling, use, surgical technique applied or for any other iatrogenic error caused by the implanting surgeon.

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:





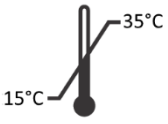
1. Place the label with UDI 2D barcode on the Implant card.
2. Fill in the date of implantation
3. Mark the implanted eye - left (OS) or right (OD).
4. Fill in the name of patient or patient ID.
5. Fill in the name and address of the healthcare institution / provider.
6. Fill in the device name.

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	 Sterilized using ethylene oxide
 Temperature limit	 Date of manufacture	 Single sterile barrier system with protective packaging inside
 Medical device	 Unique Device Identifier	 Caution

MANUFACTURER

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Any adverse events that the lens may have caused, any serious incident should be reported to Medicontur's Quality Assurance at QA@medicontur.hu 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.