



MEDICONTUR E-IFU

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MEDICONTUR "FLEX" HYDROPHOBIC MONOFOCAL INTRAOCULAR LENSES PRELOADED IN A SINGLE USE INJECTOR

INSTRUCTIONS FOR USE

EN

DESCRIPTION

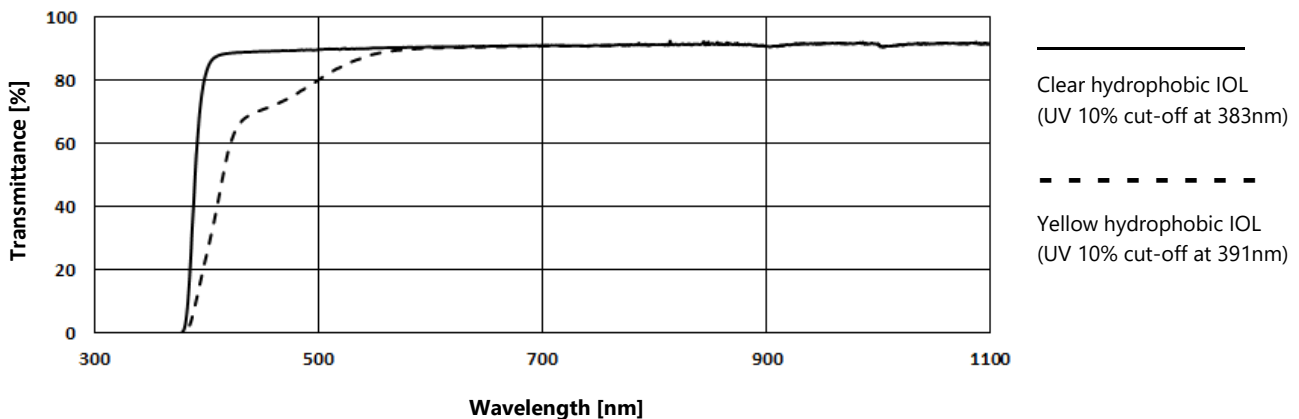
Consists of one, single piece, sterile, foldable acrylic intraocular lens (IOL) with UV-absorbent, preloaded in an assembled injector. Yellow IOLs have a blue-light filtering chromophore covalently bonded to the material (see Graph 1). These models are marked with 'Y' in the product code. Different models are controlled individually for their optical and mechanical properties.

Injector parts: injector body, adapter, rotatable ring, cartridge, stopper, plunger with a soft tip, spring.

Toric models: In case of monotoric lenses the toric surface is on the posterior side.

EDOF (Extended Depth Of Focus) lenses carry an additional optical function on the central portion of the anterior surface of the otherwise monofocal optic as a wavefront-shaping element in order to create an extended focal range.

Graph 1: Average spectral transmittance of Medicontur IOLs



MODELS

Code	Material	Design	Estimated corneal incision size
877PA	hydrophobic	monofocal	2.2 mm
877PAY	hydrophobic	monofocal	2.2 mm
860PA	hydrophobic	monofocal	2.2 mm
860PAY	hydrophobic	monofocal	2.2 mm
877PT	hydrophobic	toric	2.2 mm
877PTY	hydrophobic	toric	2.2 mm
860PT	hydrophobic	toric	2.2 mm
860PTY	hydrophobic	toric	2.2 mm
877PEY	hydrophobic	EDOF	2.2 mm
860PEY	hydrophobic	EDOF	2.2 mm
877PETY	hydrophobic	EDOF toric	2.2 mm
860PETY	hydrophobic	EDOF toric	2.2 mm

PACKAGING

The IOL is packaged in the injector and the entire system is packaged in a protective blister, sterilized by ethylene oxide.

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 expiration date.

INTENDED PURPOSE

MEDICONTUR Posterior Chamber Intraocular Lenses are intended for primary implantation into the capsular bag in the posterior chamber of the eye to replace the human crystalline lens in adult patients.

MEDICAL INDICATION

MEDICONTUR POSTERIOR CHAMBER Intraocular Lenses are indicated for visual correction of aphakia secondary to removal of the crystalline lens in adult patients

Toric models: Medicontur Toric IOLs are indicated for patients with corneal astigmatism who aspire to have improved uncorrected distance vision and reduction of residual refractive cylinder.

EDOF models: Medicontur EDOF IOLs are indicated for patients who aspire to have improved intermediate vision with uncompromised distance vision.

PATIENT TARGET GROUP

Aphakic adult patients (18 years old and older)

INTENDED USERS

Medicontur IOLS must be handled and implanted by a qualified and properly trained ophthalmic surgeon

CONTRAINDICATIONS

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

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:

- Perioperative complications such as posterior capsular rupture, zonular separation or damage, significant vitreous loss, significant anterior chamber bleeding or choroidal hemorrhage
- Extremely shallow anterior chamber
- Severe corneal dystrophy
- Severe optic nerve atrophy
- Color vision deficiencies

- Uncontrolled intraocular pressure or glaucoma
- Recurrent anterior or posterior segment inflammation of unknown etiology
- Diabetic retinopathy
- Iris neovascularization
- Previous retinal detachment
- Clinically significant macular or Retinal Pigment Epithelium changes
- Amblyopia
- Pseudoexfoliative syndrome
- Polaris posterior cataract
- Zonulolysis
- Phakodonesis
- Current or previous use of systemic alpha-1a adrenergic antagonist (especially tamsulosin)
- Pregnancy
- Choroidal hemorrhage
- Retinal detachment
- Bacterial or viral endophthalmitis

TORIC MODELS

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

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

- Corneal damage or edema
- Secondary glaucoma

Preoperative

- Iris trauma
- Pupillary block
- Hemorrhage

Postoperative

- Intraocular infection
- IOL replacement or extraction
- Uveitis
- Cystoid macular edema
- 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
- Longer IOL preparation process
- Macular degeneration leading to blindness in long term (years)
- Postoperative period
- TASS, endophthalmitis

WARNINGS

- Medicontur IOLS are designed to be implanted into the capsular bag only. There is no clinical data demonstrating the safety and efficacy of an implantation in the ciliary sulcus.
- 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 re-use the lens or any part of the system 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.
- 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 ultraviolet rays.
- 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.

TORIC MODELS

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

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 formula 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.

For Toric IOLs, the use of a computerized/web-based toric calculator is highly recommended to ensure the best optical outcome.

For further information please refer to <http://www.medicontur.com>.

DIRECTIONS FOR USE

1. Open the outer package to remove the blister containing the injector system with the IOL and verify that the information on the blister is consistent with the outer package labeling (e.g. power, model, SN).
2. Open the blister and remove the injector system with the IOL in a sterile environment.
3. Fully introduce the cannula (23-27G) of a syringe filled with viscoelastic material into the small aperture indicated with '1' (Fig. 1), maintaining a slight pressure on the cannula tip. Inject the viscoelastic solution through the aperture. The injected quantity of visco is sufficient as soon as the IOL optic is covered by the viscoelastic solution.
4. Keep the injector in this state for a minimum of 3 minutes.
5. Turn the transparent rotatable ring as indicated by the flat arrow marked with '2' counter-clockwise by 90 degrees until it snaps into place with a distinct "click" (Fig. 2a).

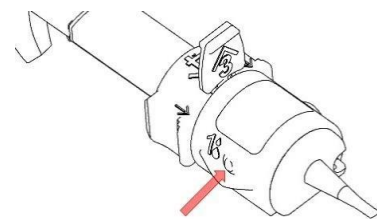


Fig. 1

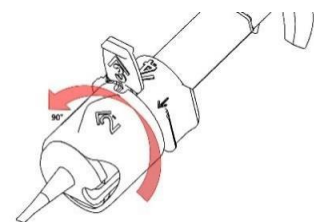
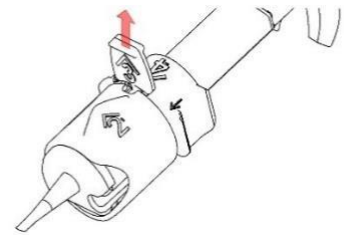


Fig. 2a

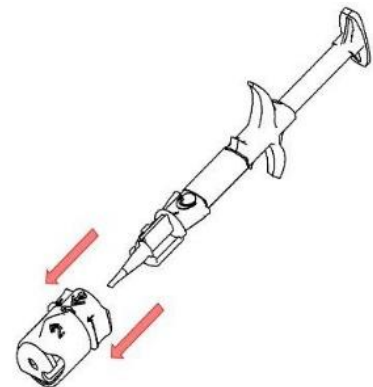
6. Remove the red stopper indicated with '3' by pulling and discard it (Fig. 2b).

Fig. 2b



7. Remove the adapter together with the rotatable ring as indicated by '4' (Fig. 3) by pulling it off and discard it.

Fig. 3



8. Push the plunger forward in a slow, controlled manner. Anticipate a slight initial resistance. Excessive resistance could indicate a trapped lens.
9. Push the plunger continuously and do not pause until the optic exits the cartridge tip.
10. With the nozzle tip bevel facing down, inject the IOL applying continuous light pressure on the plunger.
11. Once the lens optic exits the cartridge tip, stop pressing and let the trailing haptic follow the optic.
12. Carefully withdraw the cartridge nozzle from the eye once the injection process is completed.







NOTE



- Balanced Salt Solution alone should not be used as lubricant.
- When pressing the plunger, too much resistance may indicate a trapped lens.
- Do not stop the injection after you have started implanting the lens. The entire process should be one continuous process without interruption.
- If the IOL blocks the injector, discard the injector and the IOL.
- Discard the injector after use.
- The product or its waste material should be disposed of in accordance with local/national regulations and requirements.

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:











	_____	2
	<input type="checkbox"/>	3
	<input type="checkbox"/>	
	_____	4
	_____	5
	www.medicontur.com/patientimplantinfo	

┌		└
	1	
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	_____	6
	Medicontur Medical Engineering Ltd Herceghalmi út 1., 2072 Zsámbék, Hungary www.medicontur.com	













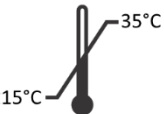





1. Place the label with UDI 2D barcode on the Implant card.
2. Fill in the date of implantation
3. Mark the implanted eye - left (OS) or right (OD).
4. Fill in the name of patient or patient ID.
5. Fill in the name and address of the healthcare institution / provider.
6. Fill in the medical device name.

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 event 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.

LAST UPDATE:

May 2021 Revision number: 05

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