MEDICONTUR E-IFU

MEDICONTUR "FLEX" PRELOADED HYDROPHILIC INTRAOCULAR LENSES

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DESCRIPTION

Consists of one, single piece, sterile, preloaded, 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.

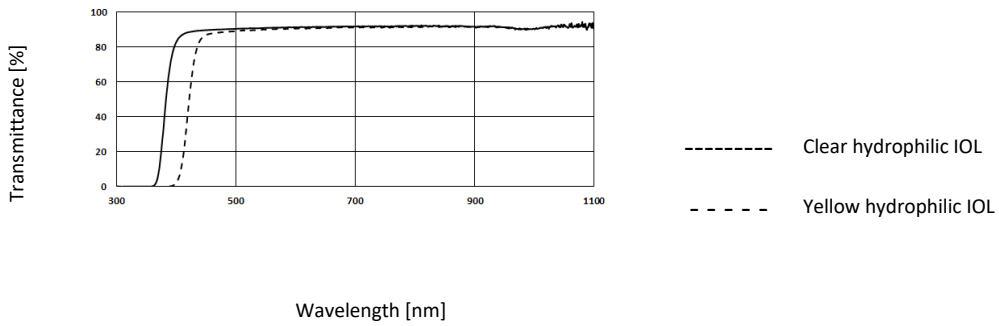
EXTENDEND DESCRIPTION - TORIC MODELS

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

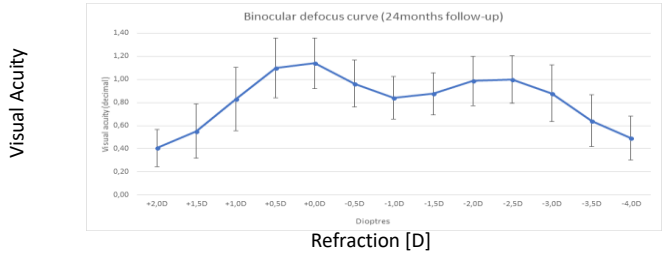
EXTENDEND DESCRIPTION - MULTIFOCAL MODELS

The anterior surface is the apodized, diffractive side of the lens. The added power for near vision is indicated on the label. For the defocus curves see Graph 2.

Graph 1: Average spectral transmittance of Medicontur IOLs



Graph 2: Average binocular defocus curve for Medicontur's Multifocal IOLs (with +3.5 D Addition)



NOTE

Medicontur Preloaded Hydrophilic Intraocular Lenses are dedicated for use uniquely with the MEDJET PIL-MA single use injector system. The two major components (the IOL and the injector) of this preloaded injection system are packaged and sterilized separately. Before using the devices please read both Instructions For Use carefully.

MONOFOCAL MODELS

Code	Brand	Material	Design
677P	Bi-Flex	hydrophilic	monofocal
677PY	Bi-Flex	hydrophilic	monofocal
690P	Z-Flex	hydrophilic	monofocal
690PY	Z-Flex	hydrophilic	monofocal
640P	Q-Flex	hydrophilic	monofocal
640PY	Q-Flex	hydrophilic	monofocal

TORIC MODELS

Code	Brand	Material	Design
677PT	Bi-Flex T	hydrophilic	monotoric
677PTY	Bi-Flex T	hydrophilic	monotoric
677PTB	Bi-Flex T	hydrophilic	bitoric
677PTBY	Bi-Flex T	hydrophilic	bitoric
690PT	Z-Flex T	hydrophilic	monotoric
690PTY	Z-Flex T	hydrophilic	monotoric
690PTB	Z-Flex T	hydrophilic	bitoric
690PTBY	Z-Flex T	hydrophilic	bitoric

MULTIFOCAL MODELS

Code	Brand	Material	Design
677PM	Bi-Flex M	hydrophilic	multifocal
677PMY	Bi-Flex M	hydrophilic	multifocal
690PM	Z-Flex M	hydrophilic	multifocal
690PMY	Z-Flex M	hydrophilic	multifocal
640PM	Q-Flex M	hydrophilic	multifocal
640PMY	Q-Flex M	hydrophilic	multifocal

MULTIFOCAL TORIC MODELS

Code	Brand	Material	Design
677PMT	Bi-Flex MT	hydrophilic	multifocal monotoric
677PMTY	Bi-Flex MT	hydrophilic	multifocal monotoric
690PMT	Z-Flex MT	hydrophilic	multifocal monotoric
690PMTY	Z-Flex MT	hydrophilic	multifocal monotoric

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.

INDICATIONS

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

EXTENDED INDICATIONS - TORIC MODELS

- Toric IOLs are recommended for patients who aspire to have improved uncorrected distance vision and reduction of residual refractive cylinder.
- Toric design Medicontur IOL models are implanted in astigmatic eyes.

EXTENDED INDICATIONS - MULTIFOCAL MODELS

- Multifocal IOLs are recommended for patients who aspire to have near, intermediate and distance vision with increased spectacle independence.
- Multifocal design Medicontur IOL models are implanted in presbyopic eyes regardless of whether there is cataract or not.

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 - TORIC MODELS

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

CONTRAINDICATIONS - MULTIFOCAL MODELS

- Individuals who drive at night for a living or whose occupation or hobbies depend on good
- Individuals who need very good near vision in semidarkness
- Individuals who are professional or non-professional pilots
- Keratoconus
- Age-related Macular Degeneration
- Monocular patients
- Any eye disease in which postoperative visual acuity is not expected to be better than 0.5 (e.g. amblyopia, nystagmus, retinitis pigmentosa, aniridia, exentric pupil)

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).
- 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.

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.

WARNINGS - MULTIFOCAL MODELS

- Manage patient selection and operative technique carefully to ensure that the total postoperative corneal astigmatism does not exceed 1.5 diopters. Patients with pupil size less than 2.5 mm may not obtain any near vision benefit.
- 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. 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://toriccalculator.net or http://www.medicontur.com.

For Multifocal lenses target emmetropia.

DIRECTIONS FOR USE

1. Open the outer package to remove the protective blister pack and verify that the IOL container information is consistent with the outer package labeling (e.g. power, model, SN). At the same time ensure that the appropriate, unexpired, sterile and unused MEDJET PIL-MA injection system is available.
2. Open the blister at the marked end and remove the lens container in a sterile environment.
3. Remove the peel-off aluminum foil from the wet lens container while holding the container horizontally.
4. For loading and injection of the lens please refer to the Instructions for Use enclosed with the MEDJET PIL-MA injection system.

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 Sterilized using steam or dry heat		

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.