



MEDICONTUR E-IFU

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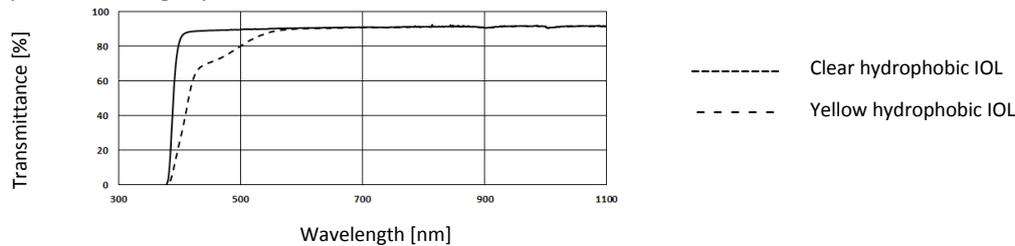
MEDICONTUR “FLEX” HYDROPHOBIC MONOFOCAL INTRAOCULAR LENSES PRELOADED IN A SINGLE USE EN INJECTOR

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.

The parts of the injector are: injector body, adapter, rotatable ring, cartridge, stopper, plunger with a soft tip, spring.

Graph 1: Average spectral transmittance of Medicontur IOLs



MODELS

Code	Brand	Material	Design	Estimated corneal incision size
877PA	Bi-Flex	hydrophobic	monofocal	2.2 mm
877PAY	Bi-Flex	hydrophobic	monofocal	2.2 mm
860PA	Z-Flex	hydrophobic	monofocal	2.2 mm
860PAY	Z-Flex	hydrophobic	monofocal	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 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.

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

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, 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

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 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.
- Store the unopened IOL box in a dry place, away from moisture and direct sunlight at room temperature (15-35°C).
- 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.

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 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 (23G) 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 dispersive viscoelastic solution (preferably HPMC) through the aperture. The injected quantity of visco is sufficient as soon as the two flows (drops) of the viscoelastic solution meet on top of the lens (become confluent).

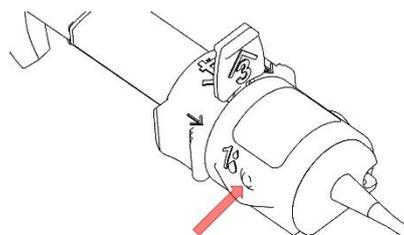


Fig. 1

4. Turn the transparent rotatable ring as indicated by the flat arrow marked with '2' counterclockwise by 90 degrees until it snaps into place with a distinct "click" (Fig. 2a).

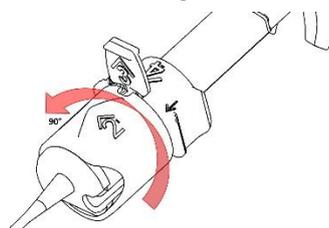


Fig. 2a

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

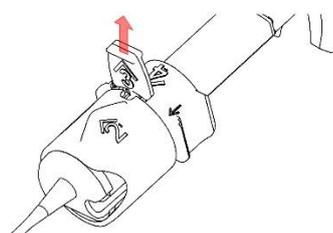


Fig. 2b

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

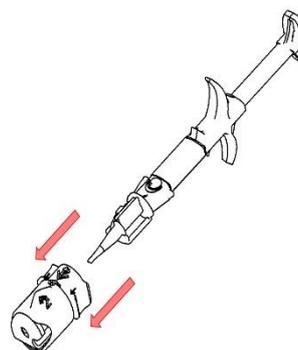


Fig. 3

7. Push the plunger forward in a slow, controlled manner. Anticipate a slight initial resistance. Excessive resistance could indicate a trapped lens.
8. With the nozzle tip bevel facing down, inject the IOL applying continuous light pressure on the plunger.
9. When the lens exits the cartridge nozzle, stop pressing the plunger and carefully withdraw the cartridge nozzle tip from the eye.

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 system, 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.

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.

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 certified	 Keep dry	 Do not re-use
 Keep away from sunlight	 Consult instructions for use	 Do not re-sterilize
 Serial number	 Use by date	 Store at room temperature
 Do not use if package is damaged	 Manufacturer	 Do not freeze
 Sterilized using ethylene oxide		

MANUFACTURER

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