MEDICONTUR E-IFU

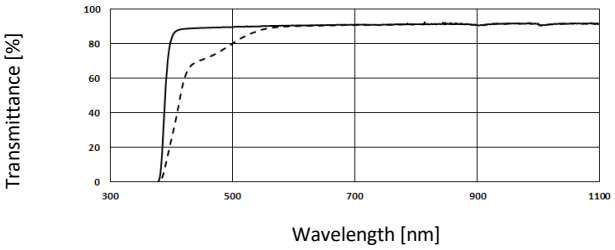
MEDICONTUR "FLEX" HYDROPHOBIC MONOFOCAL INTRAOCULAR LENSES PRELOADED IN A SINGLE USE INJECTOR EN

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.

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



---------- Clear hydrophobic IOL (UV 10% cut-off is 383nm)

- - - - - Yellow hydrophobic IOL (UV 10% cut-off is 391nm)

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 expiration date.

INTENDED USE

Optical implant intended to be positioned in the posterior chamber of the eye, for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients.

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, 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 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.
- 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.

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.

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).

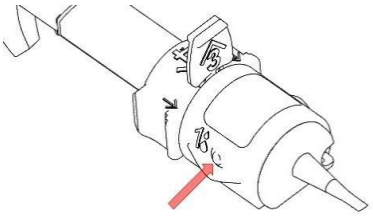


Fig. 1

4. 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' counterclockwise by 90 degrees until it snaps into place with a distinct "click" (Fig. 2a).

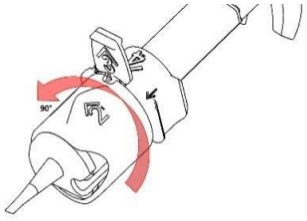


Fig. 2a

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

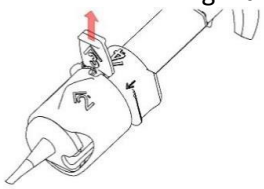


Fig. 2a

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

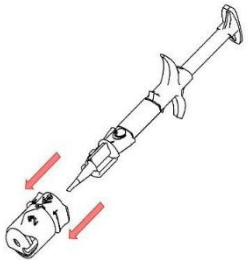


Fig. 3

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.

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 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 EO Sterilized using ethylene oxide		

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.