MEDICONTUR E-IFU

MEDICONTUR MEDJET PIL-MA SINGLE USE INJECTION SYSTEM EN

DESCRIPTION

Consists of one, single use, sterile, disposable device (injector) for the implantation of the "FLEX" preloaded, foldable, hydrophilic intraocular lenses (IOL) into the eye. The injector consists of the following parts: the injector body, a cartridge, a pushing rod with a soft tip on it and a red stopper.

NOTE

The Medicontur PIL-MA injector system is dedicated for use exclusively with the Medicontur “FLEX” Preloaded Hydrophilic Intraocular Lenses. 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.

MODELS

Model	Applicable IOLs	Estimated corneal incision size
MEDJET PIL-MA	Bi-Flex 677P(M)(T)(Y)	2.2 mm
	Z-Flex 690P(M)(T)(Y)	
	Q-Flex 640P(M)(Y)	

PACKAGING

The injection system is packaged in a protective blister, sterilized by ethylene oxide.

EXPIRATION DATE

Medicontur injectors are sterile unless their primary packaging is damaged. Do not use an injector after its expiry date.

INDICATIONS

Medicontur MEDJET PIL-MA injectors are indicated for implantation of Medicontur “FLEX” Preloaded Hydrophilic IOLs into the posterior chamber (capsular bag) of an adult eye after the removal of the crystalline lens.

CONTRAINDICATIONS

There are no known contraindications for the use of injectors during the implantation of a foldable IOL.

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 any part of the system by any method.
- Do not use the system if the packaging is damaged or wet and the sterility of the device may have been compromised.
- Store the unopened injector packaging in a dry place, away from moisture and direct sunlight at room temperature (15-35°C) and a minimum of 35% relative humidity.
- 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.
- Patients should be advised that unexpected outcomes may necessitate additional surgical intervention.

DIRECTIONS FOR USE

1. Open the outer package to remove the blister containing the injecton system and verify that the inormation on the blister is consistent with the outer package labeling (e.g. model, lot number). At the same time ensure that the appropriate, unexpired, sterile Medicontur “FLEX” Preloaded IOL is available.

2. Open the blister and remove the injector system in a sterile environment. Prepare the IOL container as described in its Instructions for Use.
3. Align the arrows on the injector's red stopper and the open wet IOL container for correct positioning. Insert the injector with a firm downward motion as shown in Fig. 1/a until it clicks.

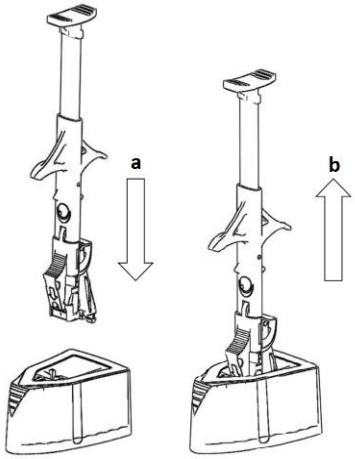

Fig. 1

4. Pull out the injector as shown in Fig. 1/b and check that the lens holder is loaded in the injector.
5. Carefully release the cartridge nozzle from the hook. Make sure you do not damage the nozzle tip. Fold up the cartridge nozzle by 180 degrees until it snaps into place, as shown in Fig. 2.

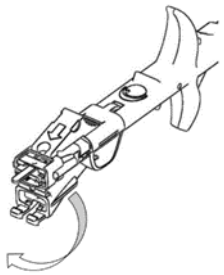

Fig. 2

6. Push the red stopper forward until it clicks to secure the cartridge nozzle and at the same time to release the arretation of the pushing rod, as shown in Fig. 3. Avoid premature pushing of the rod which is freely movable after this action.

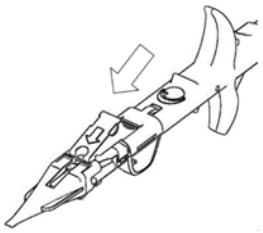

Fig. 3

7. Introduce the cannula (23G or bigger) of a syringe filled with viscoelastic material into the small aperture in front of the red stopper. Inject the viscoelastic material through the aperture as shown in Fig. 4. Filling the cartridge nozzle up halfway should suffice.

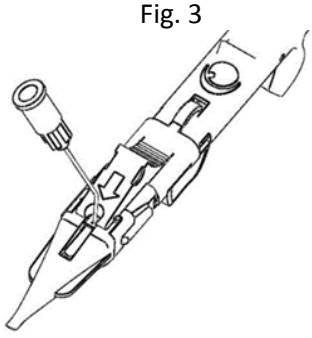

Fig. 4

8. Push the plunger forward in a slow, controlled manner. Anticipate a slight initial resistance. Excessive resistance could indicate a trapped lens.
9. With the nozzle tip bevel facing down, inject the IOL applying continuous light pressure on the plunger.
10. 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.
- 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 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.