



MEDICONTUR E-IFU

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MEDICONTUR MEDJET PIL-MA SINGLE USE INJECTOR

INSTRUCTIONS FOR USE

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 injection 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	677P(M)(T)(Y)	2.2 mm
	690P(M)(T)(Y)	
	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 expiration date.

INTENDED PURPOSE

The MediconTur MedJet PIL-MA injector is intended to be used by a trained ophthalmic surgeon for implantation of MediconTur hydrophilic foldable IOLs into the human eye.

MEDICAL INDICATION

The MediconTur MedJet PIL-MA injectors are indicated for implantation of a foldable IOL into the eye of a human adult, by injection through a corneal incision not wider than 2.5 mm, during the course of an ophthalmic surgery.

CONTRAINDICATIONS

There are no known contraindications for the use of injectors during the implantation of a foldable IOL [when used as recommended](#).

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:

- Potential damage of the eye tissue
- Potential damage of the parts of the anterior/posterior chamber including tear of capsular bag
- TASS, endophthalmitis

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.
- DO NOT USE the product if the package was unintentionally opened before use.
- Any occasional reuse must be avoided as it may pose serious health risk either by non-sterility or by any mechanical defect caused by the previous use.
- Store the unopened injector packaging in a dry place, away from moisture and direct sunlight 15-35°C.
- 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 injection system and verify that the information on the blister is consistent with the outer package labeling (e.g. model, SN number). At the same time ensure that the appropriate, unexpired, sterile Medicontur "FLEX" Preloaded IOL is available.
2. Open the blister and remove the injection system in a sterile environment. Prepare the IOL container as described in its Instructions for Use.

3. Open the IOL container and inject viscoelastic material into the lens holder, while it is still in the container. Do not enter the cannula into the lens holder to avoid any damage of the IOL, as shown in Fig. 1.

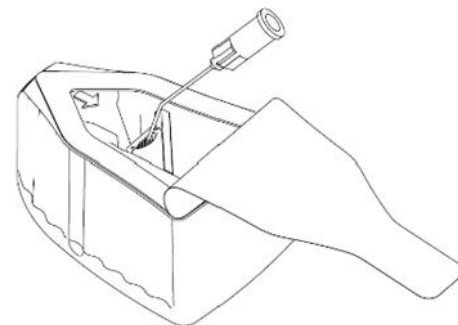


Fig. 1

4. Align the arrows on the injector's red stopper and the IOL container for correct positioning. Insert the injector with a firm downward motion as shown in Fig. 2/a until it clicks. Pull out the injector as shown in Fig. 2/b and check that the lens holder is loaded in the injector.

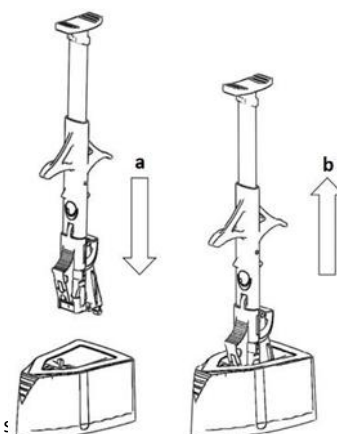
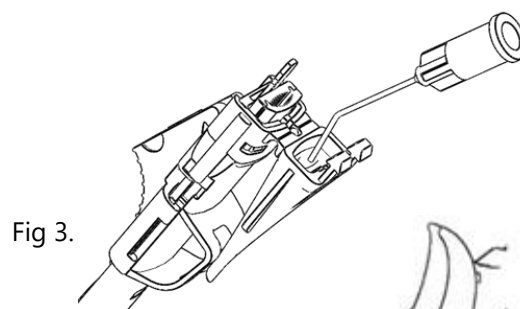


Fig. 2

- Inject viscoelastic material into the cartridge nozzle from the back side, as shown in Fig. 3



- 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. 4.

Fig 3.

Fig. 4

- Push the red stopper forward until it clicks to secure the cartridge nozzle and at the same time to release the pushing rod, as shown in Fig. 5. Avoid premature pushing of the rod which is freely movable after this action.

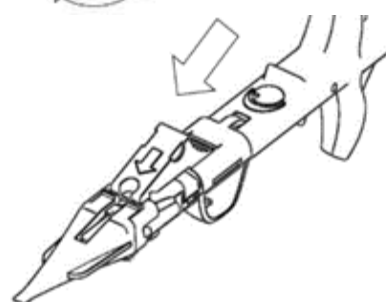
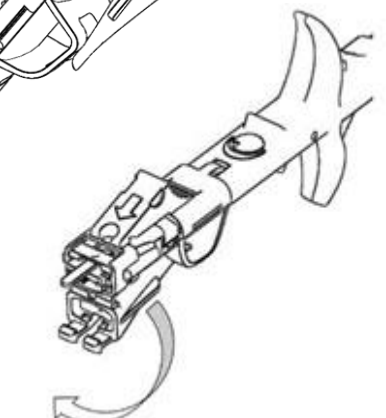
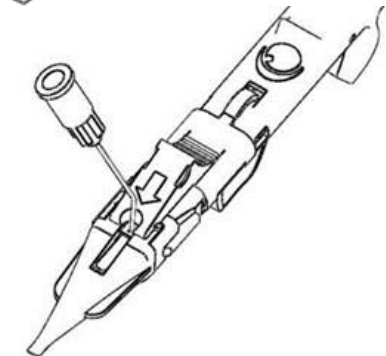


Fig 5.

- 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. 6. Filling the cartridge nozzle up halfway should suffice.

Fig. 6



- Push the plunger slowly forward and watch the IOL in front of the plunger progressing smoothly before reaching the end of the "cartridge wings".

- Once the IOL reaches the "cartridge wings" as shown in Fig. 7, stop pushing and pull the plunger back to the end. Push the plunger again to remove any air from the nozzle. Enter the eye and then continue pushing slowly. If you experience too much resistance at any phase of the injection, or you can see a part of the haptic trapped between the red soft tip and the cartridge wall, pull the plunger back a few millimeters and then push it again.

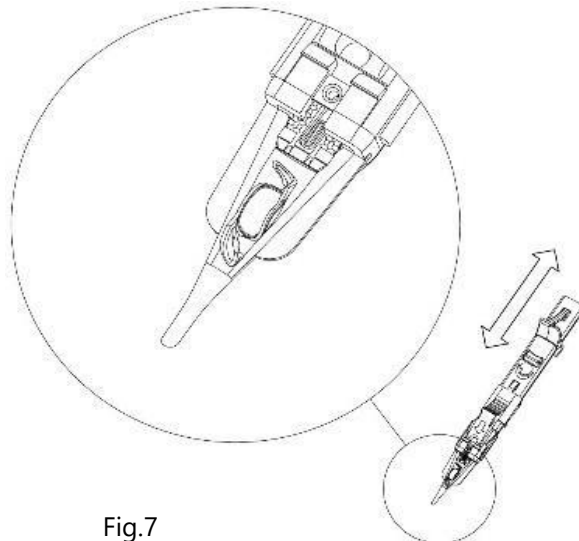


Fig.7

11. With the nozzle tip bevel facing down, inject the IOL applying continuous light pressure on the plunger.

12. When the lens optic 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, 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.

SYMBOLS

<p>CE certified</p>	<p>Keep dry</p>	<p>Do not re-use</p>
<p>Keep away from sunlight</p>	<p>Consult instructions for use</p>	<p>Do not re-sterilize</p>
<p>Serial Number</p>	<p>Use by date</p>	<p>Sterilized using ethylene oxide</p>
<p>Do not use if package is damaged</p>	<p>Manufacturer</p>	<p>Temperature limit</p>

MANUFACTURER

Medicontur Medical Engineering Ltd. [Herceghalmi út 1., 2072 Zsámbék, HUNGARY](#)

Phone: +36 23 56 55 55; Fax: +36 23 56 55 56

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.

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