# MEDICONTUR E-IFU

# MEDICONTUR MEDJET MC, MB, MA, MX SINGLE USE INJECTOR SYSTEM

**EN**

## DESCRIPTION

Consists of one, single use, sterile, disposable device for the implantation of a foldable hydrophilic and hydrophobic intraocular lens (IOL) into the eye. The device consists of two parts: the assembled injector and the cartridge. The injector has 4 different parts: the housing, a pushing rod, a plunger and a spring.

## MODELS

| Model | Outer diameter of the cartridge |
|---|---|
| MEDJET MC $^{1.6}$ | 1.40 mm |
| MEDJET MB $^{1.8}$ | 1.62 mm |
| MEDJET MA $^{2.2}$ | 1.74 mm |
| MEDJET MX $^{2.4}$ | 1.98 mm |

## PACKAGING

The injection system is packaged in a protective plastic tray which is sealed with a blister foil, sterilized by ethylene oxide. Medicontur injectors are sterile unless their primary packaging is damaged.

## EXPIRATION DATE

The expiry date is printed on the carton/blister and the primary container. Do not use an injector after its expiry date.

## INTENDED USE

The Medicontur Medjet injectors are intended to be used by a trained ophthalmic surgeon for implantation of a foldable intraocular lens into the human eye.

## INDICATION

The Medicontur Medjet 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.

## WARNINGS

- Examine the package labels carefully for information about the model 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 and verify that the information is consistent with the outer package labeling (e.g. model, LOT number). At the same time ensure that the appropriate, unexpired, sterile Medicontur IOL is available.

2. Open the protective blister and remove the injector system in a sterile environment.
3. Open the winglets of the cartridge and fill up the nozzle with sterile viscoelastic material. Cover both halves of the loading chamber with the viscoelastic material as well.
4. For implantation of a hydrophobic intraocular lens do not use cohesive viscoelastic solution.
5. Carefully remove the lens from the lens holder using parallel tipped, non-serrated forceps. Rinse the IOL with sterile Balanced Salt Solution.
6. Position the lens in the loading chamber in a proper configuration.
   - Lenses with 2 loop haptics (e.g. Bi-Flex or Z-Flex): position the lenses in the loading chamber in a 'Z' or 'reverse-S' orientation.
   - Lenses with 4 loop haptics (e.g. Q-Flex): the orientation mark on the upper haptics must be on the right in the nozzle side of the cartridge.
7. Hold open the winglet of the cartridge, center the IOL and position the tip of the haptics under the edge of the grooves. Gently push the lens down with the forceps to ensure that the edges of the optic is securely underneath the edge of the grooves as shown in Fig. 1.

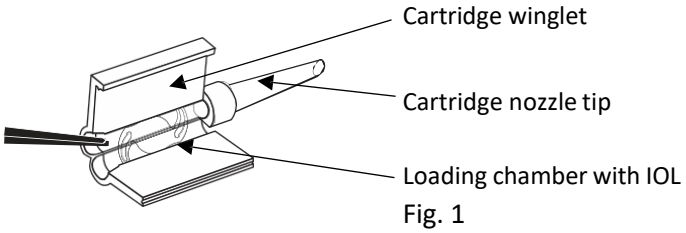

Fig. 1

8. Cover the upper surface of the lens with the viscoelastic solution. While keeping the lens in position with open forceps, gently close the winglets of the cartridge without pinching any part of the optic or haptics, before locking the winglets.
9. Press the winglets together at their base firmly until the click. Visually observe that the lens is symmetrically folded within the loading chamber.
10. Insert the locked cartridge into the loading bay of the injector body and lock the cartridge with a gentle rotation of the wings as shown in Fig. 2.

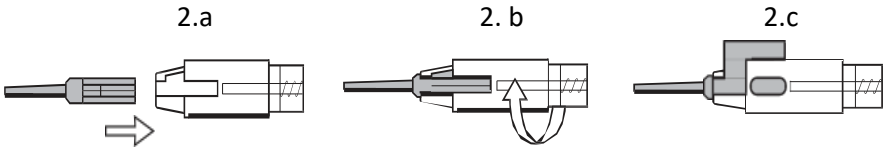

Fig. 2

11. Push the plunger forward in a slow, controlled manner. Anticipate a slight initial resistance. Excessive resistance could indicate a trapped lens.
12. Pull the plunger back a few millimeters and then push forward again. This step ensures that the lens is always grasped correctly. Proceed immediately.
13. With the nozzle tip bevel facing down, inject the IOL applying continuous light pressure on the plunger.
14. 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 closing and locking the winglets, any resistance could indicate a trapped lens.
- 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 1639 CE certified | Keep dry | Do not re-use |
| Keep away from sunlight | Consult instructions for use | Do not resterilize |
| LOT LOT 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 | Warning | |

**MANUFACTURER**

Medicontur Medical Engineering Ltd. Herceghalmi Road, H-2072 Zsámbék, HUNGARY
Phone: +36 23 56 55 55 - Fax: +36 23 56 55 56

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.