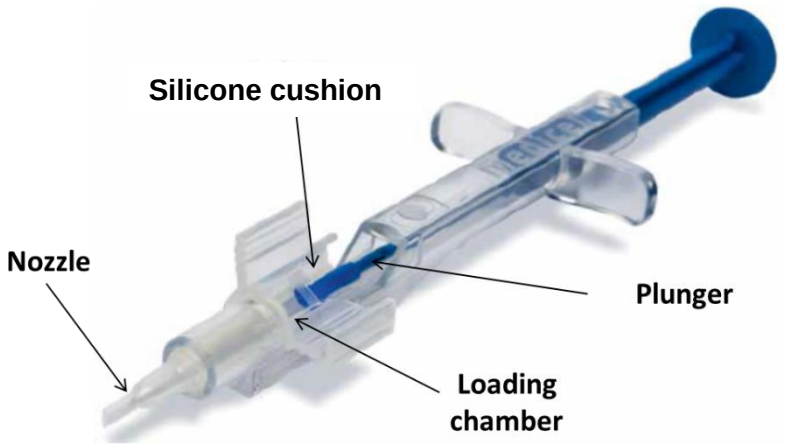
Medicel ACCUJECT™ Injector EM-IO 1.1

Instructions for use

2024-06 (en)



CE 0344

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Version of this document	2024-06 (en)

This Instructions for Use (IFU) can be downloaded from the manufacturer's website: http://infocenter.my-eyemate.com/

The Medicel ACCUJECT™ Injector EM-IO 1.1 (Basic UDI-DI: 426064817INJ4576) is an accessory of the eyemate®-IO Implant (Basic UDI-DI: 426064817IMP107A). The summary of safety and clinical performance (SSCP) for this device is available in the European database on medical devices (EUDAMED):
https://ec.europa.eu/tools/eudamed

Device Regulation: EU MDR 2017/745, Class III (accessory of AIMD)

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1 General Information

The Medicel ACCUJECT™ Injector EM-IO 1.1 (SUG010200) is a CE marked (CE 0344, 2021) accessory of the eyemate®-IO implant. It is intended to be used for implantation of the eyemate®-IO intraocular pressure sensing devices into the ciliary sulcus of the human eye. The injector consists of a handpiece, a cartridge and a nozzle.

The Medicel ACCUJECT™ Injector EM-IO 1.1 is a single-use device and is supplied EtO sterilized.

1.1 About these instructions for use (IFU)

This IFU describes the handling and use of the Medicel ACCUJECT™ Injector EM-IO 1.1 and the implantation procedure.

Please refer to the *eyemate®-IO implant IFU* for further information regarding the implant.

Read this IFU carefully and address any remaining questions to the manufacturer before using the system. The surgeon and relevant site personnel must be trained on the use of the Medicel ACCUJECT™ Injector EM-IO 1.1.

Upon IFU download: Ensure that the IFUs are obtained from the manufacturer's website: http://infocenter.my-eyemate.com/

WARNING!

Read this IFU carefully and follow the instructions!

1.2 Symbols used in this instruction for use

WARNING!

Failure to observe this warning may result in serious injury or personal injury.

1.3 Acronyms used in these instructions for use

AIMD	Active Implantable Medical Device
IFU	Instructions for use
IOL	Intraocular lens
WTW	White-to-white

2 Description of Medicel ACCUJECT™ Injector EM-IO 1.1

Medicel ACCUJECT™ Injector EM-IO 1.1 is a surgical instrument intended to be used for implantation of the eyemate®-IO device. It consists of a handpiece with a pre-mounted plunger tip ("silicone cushion") on the plunger, a cartridge with a loading chamber and wings as well as a nozzle (**Figure 1**).

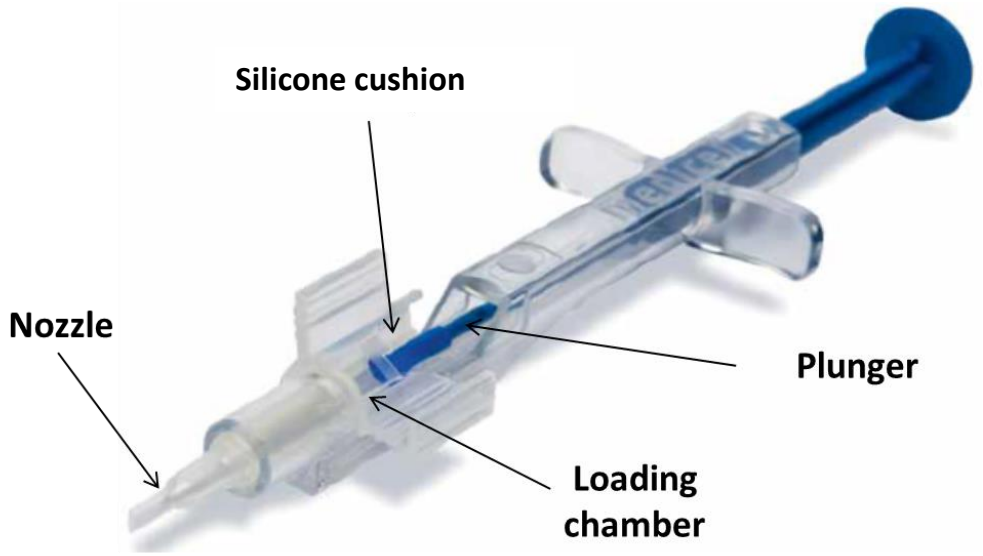


Figure 1: Medicel ACCUJECT™ Injector EM-IO 1.1.

Intended user and use environment

The Medicel ACCUJECT™ Injector EM-IO 1.1 is only to be used by specially trained, qualified and experienced ophthalmic surgeons. Contact the manufacturer for surgeon training details.

The injector is used in standard cataract surgery setting in *Healthcare Facility Environment*.

3 Indications, contraindications, warnings and safety information

3.1 Indications

The target population are patients scheduled for eyemate®-IO intraocular pressure sensor implantation.

3.2 Contraindications

WARNING!

Observe the contraindications!

Do not use the injector in patients contraindicated for the eyemate®-IO implantation.

3.3 ⚠ Warnings and safety information

⚠ General

- Any serious incident that occurs in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and /or patient is established. Serious incident means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat. To report serious incidents please contact complaint@implandata.com.
- Only specifically trained, qualified and experienced ophthalmic surgeons may handle the Medicel ACCUJECT™ Injector EM-IO 1.1 and eyemate®-IO implant. Contact the manufacturer for surgeon training details.
- The eyemate®-IO implant is to be exclusively implanted with the Medicel ACCUJECT™ Injector EM-IO 1.1 in accordance with the instructions provided in this IFU.
- Consult this IFU before use, as non-compliance may result in a hazardous situation for the patient and damage to the implant and/or the injector.
- Medicel ACCUJECT™ Injector EM-IO 1.1 and the eyemate®-IO implant are both single-use devices. They cannot be re-used or re-sterilized. Re-injection or re-processing may result in deterioration of the material and cause tissue injury and/or adversely affect the device functionality.

⚠ Pre-implantation handling and injector loading

- Ensure the correct eyemate®-IO implant size is selected (refer to *eyemate®-IO Implant IFU*).
- Ensure the preimplantation check of the eyemate®-IO implant is performed (refer to the *eyemate®-IO Implant IFU*)
- Inspect the sterile packaging of the eyemate®-IO implant prior to opening. Do not use if the sterile barrier is damaged.
- Inspect the sterile packaging of the Medicel ACCUJECT™ Injector EM-IO 1.1 prior to opening. Do not use if the sterile barrier is damaged.

- Inspect the injector system upon receipt. If it is damaged or defective, do not use. Contact the manufacturer to arrange a timely resupply.
- When removing the implant from the packaging take special care if the implant appears to be adhering to the packaging material. Applying excessive force will damage the implant.
- Handle the eyemate®-IO implant with care, using smooth forceps. Do not allow the implant to contact pointed, sharp or toothed instruments, to avoid permanent damage.
- Do not soak the implant in any solution other than a sterile isotonic solution or sterile physiological saline.
- Do not allow the eyemate®-IO implant to come into contact with any chemicals other than standard ophthalmic viscoelastic materials during the surgical procedure.
- Use generous amounts of ophthalmic viscoelastic material to fully cover the inner walls of the injector loading chamber and nozzle.
- Never touch the pressure sensitive area of the ASIC (**Figure 2**) to avoid permanent damage.
- Perform the implantation within 5 minutes of loading the injector. During this time, to minimize the risk of damage, the implant must remain in the loading chamber of the cartridge, rather than the tapered nozzle where the implant is more compressed.
- If the injector is not held in the correct orientation described in **section 4.2**, the eyemate®-IO device will be implanted backwards and will have to be explanted.
- A back-up Medicel ACCUJECT™ Injector EM-IO 1.1 must be available during the implantation.

⚠ Surgical considerations

- Perform the implantation only in accordance with the procedure described in **section 4.3**.
- It is crucial to ensure that the pupil is fully dilated during the eyemate®-IO injection.
- A pupil diameter of ≤9mm is not appropriate for eyemate®-IO implantation.
- Do not implant the eyemate®-IO device if complications occur during cataract surgery.
- Do not implant the eyemate®-IO device if floppy iris/iris prolapse occurs.
- Some resistance against movement is normal during the injection. However, if the eyemate®-IO implant appears to be trapped during the injection process, stop the implantation. Do not reuse the implant or the injector. Restart the injector loading using a backup eyemate®-IO implant and a backup Medicel ACCUJECT™ Injector EM-IO 1.1.

4 Preparation and implantation

4.1 eyemate®-IO implant size selection and pre-implantation check

Please refer to the *eyemate®-IO Implant IFU* for instructions on selection of the correct implant size and the pre-implantation check.

WARNING!

Do not implant the eyemate®-IO unless the correct size is selected, and the pre-implantation check is successfully performed.

4.2 Description of the assembling and loading of the Medicel ACCUJECT™ Injector EM-IO 1.1

WARNING!

- Only use smooth forceps for handling the implant and never touch the ASIC.
- Perform the implantation within 5 minutes of loading the injector. During this time, the implant must remain in the loading chamber.
- If the injector is not held in correct orientation (cartridge facing downwards), the device will be implanted backwards and will need to be explanted.
- If the implant appears to be trapped in the cartridge or nozzle during the injection process, stop the implantation procedure.
- DO NOT USE methylcellulose based viscoelastic.

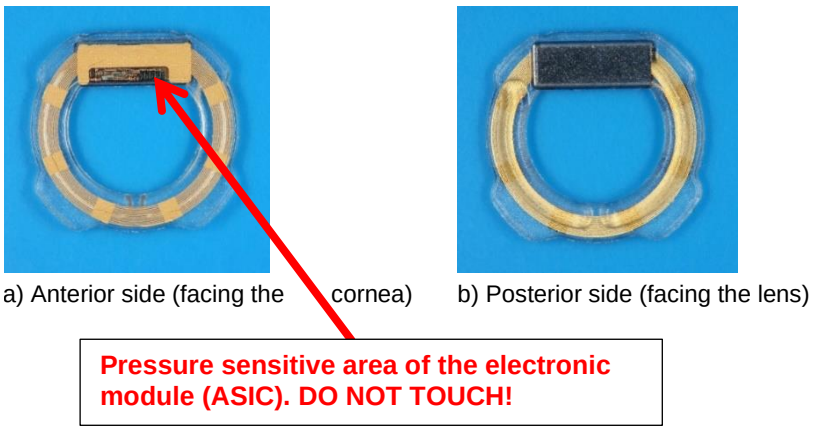
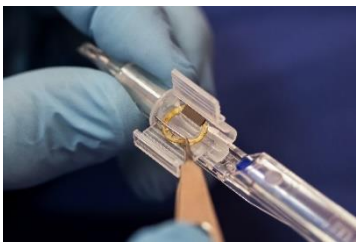


Figure 2: eyemate®-IO implant

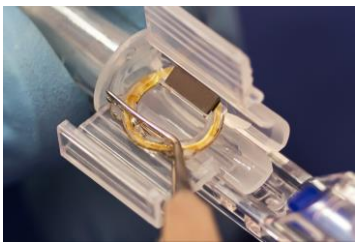
1) Inspect the Medicel ACCUJECT Injector EM-IO 1.1 upon receipt and operate/move the plunger to release the build-in transport lock.

2) Fill the loading chamber and the nozzle with generous amount of cohesive ophthalmic viscoelastic material (1% NaHA is recommended). **DO NOT USE** methylcellulose based viscoelastic).

3) Fill also the upper edge of the loading chamber with generous amount of cohesive ophthalmic viscoelastic.

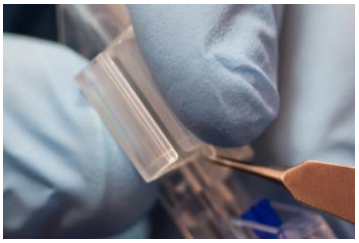


4) Using smooth forceps, hold the coil of the eyemate®-IO implant. The posterior side (**Figure 2**) of the implant is facing you. **DO NOT TOUCH** the ASIC (figure 2). Place the implant in the loading chamber of the cartridge, as close as possible to the nozzle.



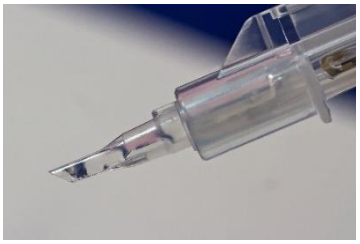
5) Gently push the upper edge of the eyemate®-IO implant into the flap of the injector cartridge…

6) …and gently push the lower edge of the eyemate®-IO implant into the flap of the injector cartridge. The eyemate®-IO implant is now positioned between the two flaps of the injector cartridge.



7) Gently close the cartridge. Ensure that the implant is fully located in the loading chamber and is not pinched between the flaps.

8) The pressure sensitive side (black golden side) of the ASIC is visible from the outside



9) Rotate the injector 180° with the **CARTRIDGE FACING DOWN-WARDS** and very gently push the plunger until the implant arrives near the nozzle tip. This allows to discard the excess viscoelastic material outside the eye.

10) The injector is now ready. Refer to the implantation procedure described in **section 4.3**.

4.3 Implantation procedure

- Cataract surgery and implantation of the artificial IOL inside the capsular bag is performed.
- Do not proceed with implantation of eyemate®-IO device if complications occur during cataract surgery or in case of floppy iris/iris prolapse.
- A 3.2 mm clear corneal or corneo-scleral incision is recommended.
- Use cohesive ophthalmic viscoelastic material (Sodium Hyaluronate) to stabilize the anterior chamber.
- Load the eyemate®-IO implant into the Medicel ACCUJECT™ Injector EM-IO 1.1 as described in **section 4.2**.
- The eyemate®-IO implant should be injected within 5 minutes of the injector loading. During this time, to minimize the risk of damage, the implant should remain in the loading chamber, rather than in the tapered nozzle where the implant is more compressed.
- It is crucial to ensure that the pupil is fully dilated. A pupil diameter of ≤9mm is not appropriate for eyemate®-IO implantation.
- Following implantation of the IOL, completely remove the viscoelastic material from behind the lens in order to allow optimum retraction of the lens in the capsular bag and provide sufficient space for eyemate®-IO implantation.
- Prior to eyemate®-IO implantation, maximize the sulcus using ophthalmic viscoelastic material in order to provide the optimum space for the implant. (DO NOT USE methylcellulose based viscoelastic)
- Use of 1.4% Sodium Hyaluronate ophthalmic viscoelastic material is recommended, since the high viscosity of this material allows more controlled implantation of the eyemate®-IO.
- Measure the incision size using a caliper. The incision needs to be large enough to allow smooth insertion of the injector nozzle without the use of excessive force and without pushing away the eye. However, if the incision is too large, the viscoelastic material will be pushed out of the eye during implantation.
- Before the injector is inserted into the eye, gently push the injector plunger forward until the implant is close to the nozzle tip. This allows removal of the excess viscoelastic material.
- Gently insert the injector tip in the ocular incision. Forceps can be used to hold the incision.
- While the eyemate®-IO implant is SLOWLY injected into the eye with one hand, use a spatula through a paracentesis with the second hand and guide the implant through the pupil, such that the implant fully unfolds behind the iris. Otherwise, if the eyemate®-IO implant unfolds in the anterior chamber, excessive manipulation will be required to move the implant into the sulcus, causing ocular injury.
- Do not rotate the eyemate®-IO implant within the ciliary sulcus.
- If needed, the incision is sutured.
- Fully remove the viscoelastic material from sulcus and the anterior chamber following implantation. The final removal of the viscoelastic must only be performed after the suturing of the incision to avoid iris prolapse.
- When implanted correctly, the anterior side of the eyemate®-IO device (**Figure 2**) faces the cornea. If the implant is placed backwards, it may cause iris abrasion and must be explanted using the procedure described below. Do not attempt to reverse the implant inside the eye.
- It is preferable to have the ASIC (**Figure 2**) in the superior position in the eye. However, if this is not the case, do not attempt to rotate the implant within the sulcus.
- Following implantation, return the unused implants in their original packaging as well as any used or damaged implants to the manufacturer.

5 How supplied

Packaging

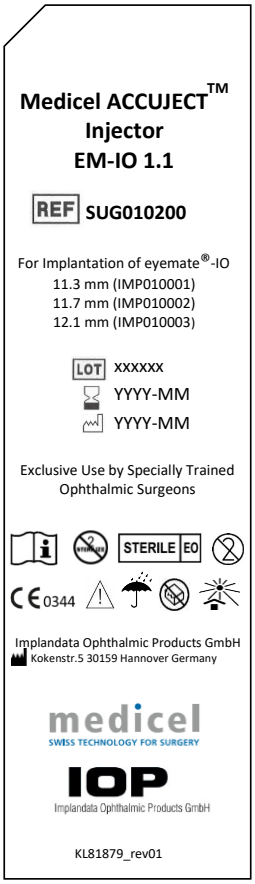
The Medicel ACCUJECT™ Injector EM-IO 1.1 is supplied EtO sterilized in a Blister Pack sealed with Tyvek.

Storage and handling

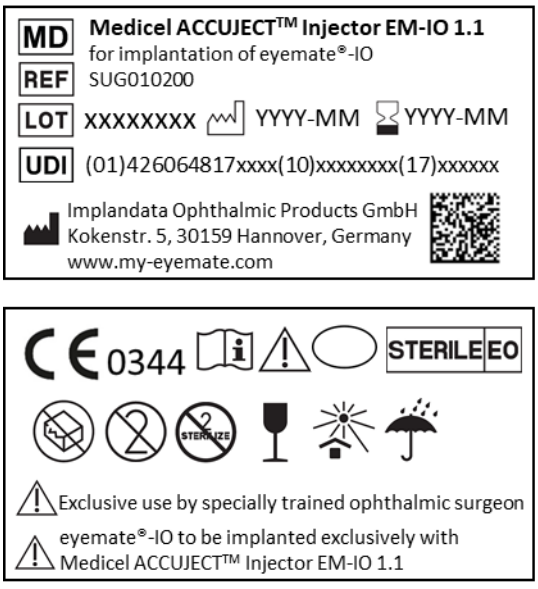
The Medicel ACCUJECT™ Injector EM-IO 1.1 must be stored in clean and dry environment. The injector components are fragile and must be handled with care.

Labels and description of symbols

The following labels are provided with the Medicel ACCUJECT™ Injector EM-IO 1.1:



Sterile packaging label



Sales packaging labels

Description of symbols			
LOT	Batch code	REF	Catalogue number
⚠	Caution	📖	Consult instructions for use

Description of symbols			
	Date of manufacture		Do not re-sterilize
	Do not re-use		Do not use if package is damaged and consult “instructions for use”
	Handle with care		Keep away from sunlight
	Keep dry		Manufacturer
	Medical device		Single sterile barrier system
	Sterilized using ethylene oxide		Unique device identification (in human-readable format and 2D data matrix)
	Use-by date		This device is in compliance with the requirements of the EU MDR 2017/745 and is CE certified by the Notified Body DEKRA B.V. with identification number 0344.

6 Specifications

The Medicel ACCUJECT Injector EM-IO 1.1 was designed and developed, and is produced by Medicel AG (Switzerland). It is a modular designed injector of which the nozzle is customized following the requirements of Implandata Ophthalmic Products GmbH.

Parameters and specifications	
Injector nozzle: Inner/outer diameter of nozzle tip/nozzle taper/bevel	2.3 x 1.5 mm / 2.7 x 1.9 mm 3.6° x 2.1° / 45°
Nozzle material (the only material in direct contact with the patient)	Medical grade polyether block amide coated with Medicoat A (Medicel AG)

7 Manufacturer

Implandata Ophthalmic Products GmbH
Kokenstrasse 5
30159 Hannover
Germany

Tel.: +49 (0) 511 2204 2580
Fax: +49 (0) 511 2204 2589
Website: www.my-eyemate.com

General inquires: info@implandata.com
Technical issues: service@implandata.com
Reporting complaints/serious incidents: complaint@implandata.com

8 Troubleshooting

In case of any issues or technical questions, please contact the manufacturer.

WARNING!

Do not attempt to repair or modify the implant or the injector!

9 Device disposal

The Medicel ACCUJECT™ Injector EM-IO 1.1 can be safely discarded using the standard procedure for handling surgical waste at the healthcare facility where the implantation takes place.