

Device Regulation: AIMDD 90/385/EEC, accessory of AIMD

The EYEMATE-IO intraocular pressure sensor (IMP010001, IMP010002 and IMP010003) is a CE marked (CE⁰³⁴⁴, 2017) active implantable medical device (AIMD). Together with the Mesograph reader device and its accessories, it is intended as a diagnostic system for users to measure the intraocular pressure (IOP). The Medicel ACCUJECT Injector EM-IO 1.1 is a CE marked (CE⁰³⁴⁴, year of authorization) accessory of AIMD, used for implantation of the EYEMATE-IO device. The injector consists of a hand-piece, a cartridge and a nozzle.

These Instructions for Use (IFU) only describe the handling and use of the Medicel ACCUJECT Injector EM-IO 1.1. Please refer to the *EYEMATE-IO Implant IFU* and *Mesograph IFU* for further instructions.

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.




 **Warning:** Read this IFU carefully and follow the instructions!

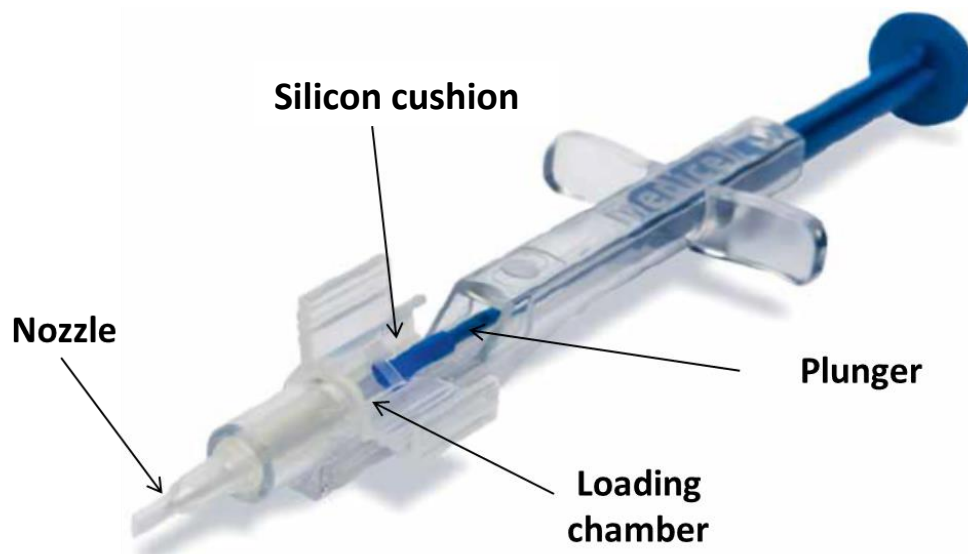
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1. Description of Medicel ACCUJECT Injector EM-IO 1.1

The 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 hand-piece with a pre-mounted plunger tip ("silicon cushion") on the plunger, a cartridge and a nozzle (figure 1). All injector components are for single use and supplied to the user EtO sterilized.

Figure 1: Medicel ACCUJECT Injector EM-IO 1.1. The injector has a modular design and consists of the injector hand-piece with pre-mounted silicon cushion on the plunger, the nozzle and the loading chamber.



2. Indications

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

3. Contraindications



Warning: Observe the contraindications!

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

4. Warnings

- Only specifically trained, qualified and experienced ophthalmic surgeons may handle the Medicel ACCUJECT Injector EM-IO 1.1 and implant. Contact the manufacturer for surgeon training details.
- The injector is only to be used with the EYEMATE-IO implant.
- Consult this IFU before loading the EYEMATE-IO implant onto the injector, as non-compliance may result in a hazardous situation for the patient and damage to the implant.
- Medicel ACCUJECT Injector EM-IO 1.1 is a single-use system delivered EtO sterilized. It cannot be re-used or re-sterilized.
- Inspect the sterile packaging prior to opening. Do not use if the sterile barrier is damaged.

5. Cautions

- 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.
- 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 6, the EYEMATE-IO device will be implanted backwards and will have to be explanted.
- A back-up sterile injector hand-piece, cartridge and nozzle must be available during the implantation procedure.
- Inspect the injector system upon receipt. If it is damaged or defective, do not use. Contact the manufacturer to arrange a timely resupply.
- Use generous amounts of ophthalmic viscoelastic material to fully cover the inner walls of the injector loading chamber and nozzle.
- Some resistance against movement is normal during the injection process. However, if the implant appears to be trapped in the cartridge or nozzle during the injection process, stop the implantation procedure. Do not reuse the implant and injector. Restart the injector loading using a backup implant and injector.

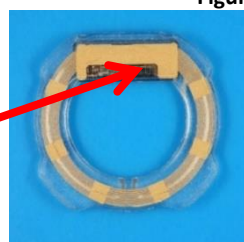
6. Description of the assembling and loading of the injector



Caution:

- Only use smooth forceps for handling the implant and never touch the ASIC.
- Ensure that a correct combination of cartridge and silicone tip is used.

Figure 2: EYEMATE-IO implant



Anterior side (facing the cornea)



Posterior side (facing the lens)

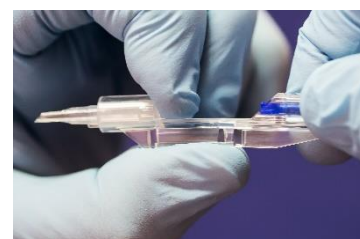
Pressure sensitive area of the ASIC. DO NOT TOUCH!



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



b) Careful mount the nozzle on the hand-piece as shown above.



c) Make sure that the nozzle is fully inserted.



d) Mount the cartridge on the hand-piece unit and open the flaps of the cartridge.



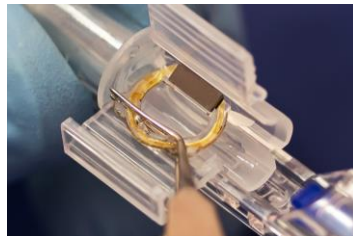
e) Fill the loading chamber as well as the nozzle with generous amount of cohesive ophthalmic viscoelastic material (1% NaHA is recommended. **DO NOT USE** methylcellulose based viscoelastic).



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



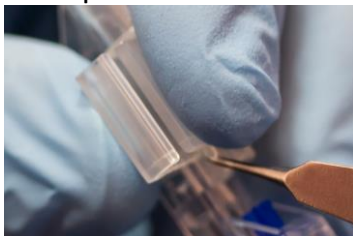
g) Using smooth forceps, hold the coil of the EYEMATE-IO implant. The posterior side (figure 2) of the implant is facing you. **DO NOT TOUCH** the ASIC (figure 2). Place the implant in the loading chamber of the cartridge, as close as possible to the nozzle.



h) Gently push the upper edge of the EYEMATE-IO implant into the flap of the injector cartridge...



i) ...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.



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




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



l) Rotate the injector 180° with the **CARTRIDGE FACING DOWNWARDS** 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.



m) The injector is now ready. Refer to *EYEMATE-IO IFU* for instructions on implantation procedure.

-  **Cautions:**
- 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 rather than the tapered nozzle where the implant is more compressed.
 - 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.

7. How supplied

Packaging














The Medicel ACCUJECT Injector EM-IO 1.1 is supplied EtO sterilized in multilayered packaging.


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.

Label

The description of the symbols are shown in the table below and the labels are shown on the following page:



	Manufacturer		Consult instructions for use
	Batch number		Caution
	Manufacturing date		Sterilized using ethylene oxide
	Expiry date		Do not re-sterilize
	Avoid exposure to direct sun		Single use
	Do not use if the sterile barrier system is damaged		Keep dry
	Device is manufactured in compliance with the requirements of the directive for active implantable medical devices 90/385/EEC and CE certified by the Notified Body DEKRA B.V. with identification number 0344		

 Implandata Ophthalmic Products GmbH	Instructions for Use (IFU) Medicel ACCUJECT Injector EM-IO 1.1	Revision A
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**Medicel ACCUJECT™
Injector
EM-IO 1.1**





REF SUG010200

For Implantation of EYEMATE-IO
11.3 mm (IMPO10001)
11.7 mm (IMPO10002)
12.1 mm (IMPO10003)

LOT XXXXXX
 YYYY-MM
 YYYY-MM

Exclusive Use by Specially Trained
Ophthalmic Surgeons

 0344




Implandata Ophthalmic Products GmbH
Kokenstr.5 30159 Hannover Germany

8. 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.

Parameter	Specification
Injector nozzle	2.3x1.5mm/2.7x1.9mm
Inner/outer diameter of nozzle tip/nozzle taper/bevel	3.6°x2.1° / 45°

9. Troubleshooting

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

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