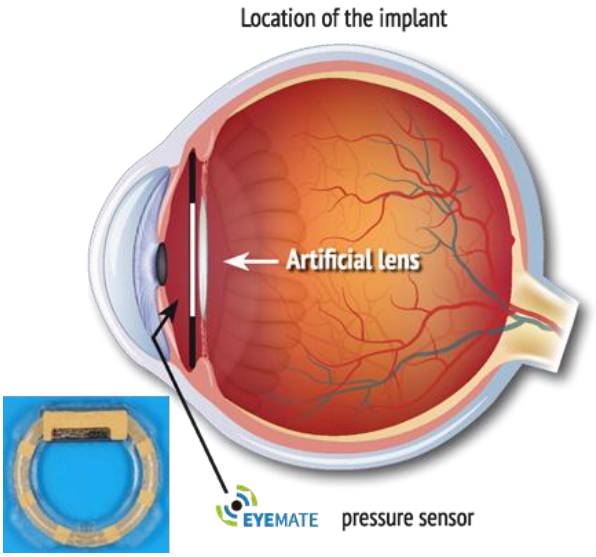
Implandata Ophthalmic Products GmbH

eyemate®-IO Implant

Instruction for use

Version 15.0 / 2021-08



CE 0344

Manufacturer	**Implandata Ophthalmic Products GmbH** Kokenstrasse 5 30159 Hannover Germany **Tel.:** +49 (0) 511 2204 2580 **Fax:** +49 (0) 511 22042589 **Website:** www.my-eyemate.com **General inquires**: info@implandata.com **Technical issues:** service@implandata.com **Reporting complaints/serious incidents**: complaint@implandata.com The complaint form can be downloaded from: http://infocenter.my-eyemate.com/
Version of this document	V15.0/2021-08

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

The summary of safety and clinical performance (SSCP) for eyemate®-IO is available in the European database on medical devices (EUDAMED) and it is linked to the basic UDI-DI: 426064817IMP107A.
https://ec.europa.eu/tools/eudamed

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

Table of contents

This page is intentionally left blank

1 General Information

The eyemate®-IO intraocular pressure sensor (IMP010001, IMP010002 and IMP010003) is a CE marked (CE 0344, 2021) active implantable medical device (AIMD). Together with the eyemate®-Reader, it is intended as a diagnostic system for users to measure the intraocular pressure (IOP).

The eyemate®-Reader (REA320100) provide wireless power and data transmission and is used for obtaining IOP measurements from the eyemate®-IO implant. A Medicel ACCUJECT™ Injector EM-IO 1.1 (SUG010200) is used for implantation of the eyemate®-IO pressuring sensing device.

The eyemate®-IO implant is single-use and is supplied EtO sterilized.

1.1 About this instruction for use

These Instructions for Use (IFU) provide information regarding the eyemate®-IO implant.

Please refer to the *Medicel ACCUJECT™ EM-IO 1.1 Injector IFU* for instructions on the implantation procedure.

Please refer to the *eyemate®-Reader IFU* for instructions on the IOP measurements procedure.

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 eyemate®-IO system.

⚠ **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
ASIC	Application specific integrated circuit (the electronic module of the implant)
EtO	Ethylene Oxide
GAT	Goldmann applanation tonometry
IFU	Instructions for use
IOL	Intraocular lens
IOP	Intraocular pressure
WTW	White-to-white

2 Description of the eyemate®-IO pressure sensing implant

The eyemate®-IO pressure sensing device is a permanent AIMD, to be implanted in the ciliary sulcus of the human eye, in combination with cataract surgery.

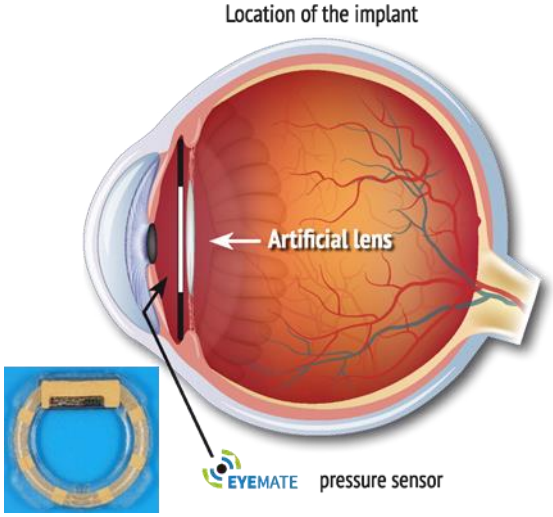


Figure 1: Location of the eyemate®-IO implant

The eyemate®-IO system directly measures the IOP or more specifically, the hydrostatic pressure of the aqueous humor, and provides digitized IOP readings in mmHg. The system can be used for frequent daily IOP measurements by the patient at home, without the need for professional assistance. The implant is powered and operated by briefly holding the eyemate®-Reader device in front of the eye (please refer to the *eyemate®-Reader IFU*).

The system is not intended to replace the current diagnostic methods for IOP measurements or intended for the diagnosis of glaucomatous damage of the optic nerve or other pathologies. The glaucoma status of a patient is to be evaluated using standard methods.

The eyemate®-IO implant is available in three sizes: 11.3mm (IMP010001), 11.7mm (IMP010002) and 12.1mm (IMP010003) in diameter. Please refer to section 5 for information regarding the implant size selection.

The life-time of the eyemate®-IO implant is 10 years from the implantation date. After this period, the non-functional device may safely remain in the eye.

Intended user and use environment

eyemate®-IO is only to be implanted by specially trained, qualified and experienced ophthalmic surgeons. Contact the manufacturer for surgeon training details.

The eyemate®-Reader, which is a portable hand-held device, is used by the patient as well as their treating medical professional in *Healthcare Facility Environment* and *Home Healthcare Environment*. Please refer to the *eyemate®-Reader IFU*.

3 Indications, contraindications, warnings and safety information

3.1 Indications and target population

The eyemate®-IO intraocular pressure sensor is an AIMD to be permanently implanted in patients with primary open angle glaucoma (POAG) and indicated cataract surgery with capsular bag IOL.

Pre-operative anterior chamber depth (ACD) ≥ 2.0 mm as measured from the corneal endothelium, and axis length of > 22 mm and ≤ 26 mm are required.

3.2 Contraindications

⚠ **Warning:** Observe the contraindications!

Do not implant the eyemate®-IO pressure sensing device in patients having any of the following contraindications:

- Patients <18 years of age
- Any type of glaucoma other that POAG
- Eyes with white-to-white (WTW) measurements smaller than 11.2mm or larger than 12.4mm
- Acute retinal detachment
- Corneal endothelial diseases e.g., Fuchs' Dystrophia
- Corneal endothelial cell density of < 2000 cells/mm²
- Pre-operative anterior chamber depth < 2.0 mm
- Axis length < 22mm or >26mm
- Diabetes Mellitus
- Existence of Marfan-Syndrome, Ehlers-Danlos-Syndrome or Weill-Marchesani-Syndrome.
- History or evidence of severe inflammatory eye diseases (i.e. uveitis, retinitis, scleritis) in either eye within 6 months prior to eyemate®-IO implantation
- Anterior chamber configuration that puts the subject at high risk of developing an angle closure glaucoma
- History of extensive keloid formation
- AIMDs in the head/neck region
- Any type of IOL other than standard capsular bag IOL implantation
- Unstable capsular support or subluxated lens
- Any contraindication for IOL implantation such as choroidal hemorrhage, concomitant severe eye diseases, excessive vitreous loss, microphthalmos, non-age-related cataract, posterior capsular rupture, severe corneal dystrophy or zonular separation
- Other medical reasons that prohibit the placement of the eyemate®-IO implant
- Complications during cataract surgery

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. For reporting a serious incident please contact complaint@implandata.com.

⚠ Handling of the eyemate®-IO implant and surgical considerations

- Only specially trained, qualified and experienced ophthalmic surgeons may perform the implantation procedure. Contact the manufacturer for surgeon training details.
- Observe the contraindications.
- Consult this IFU before eyemate®-IO implantation, as non-conformity may result in a hazardous situation for the patient or damage to the implant.
- eyemate®-IO pressure sensing device is only to be implanted using the Medicel ACCUJECT™ Injector EM-IO 1.1 according to the instructions provided in the Injector IFU.
- eyemate®-IO implant is delivered sterile and is a single-use device. It must not be reused, re-injected, re-conditioned or re-sterilized. Re-use or re-processing may result in deterioration of the material and cause tissue injury and/or adversely affect the device functionality.
- Inspect the implant packaging prior to opening. Do not use the implant if the sterile barrier shows signs of damage.
- Do not deform or alter the configuration of the implant.
- Handle the implant with care.
- The functionality of the eyemate®-IO implant must be tested prior to implantation. Implant the device only if a pre-implantation measurement within the range of ±2mmHg is obtained.
- Do not allow the eyemate®-IO implant to come into contact with pointed, sharp or toothed instruments, as doing so will cause permanent damage to the implant.
- Never touch the pressure sensitive area of the electronic module (ASIC, figure 2) to avoid permanent damage.
- 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.
- Do not allow the eyemate®-IO implant to come into contact with any chemicals other than standard ophthalmic viscoelastic materials during the surgical procedure.
- Do not soak the implant in any solution other than a sterile isotonic solution or sterile physiological saline.
- It is crucial to ensure that the pupil is fully dilated during implantation. A pupil diameter of ≤9 mm 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.

⚠ Environmental conditions

- Implant operates correctly within the absolute pressure range of 800-1150 hPa. Therefore, at altitudes above 1700 meters reliable measurements cannot be obtained.
- Instruct the patient to avoid activities such as scuba-diving. Absolute pressure beyond 2000 hPa (10 meters underwater) will permanently damage the implant.

⚠ eyemate®-IO calibration

- Following implantation, following any ocular procedure and at least once a year the correct function of the eyemate®-IO implant must be confirmed by an experienced and qualified specialist using Goldmann applanation tonometry (GAT). The average of 3 eyemate®-IO measurements are compared to one GAT measurement and adjusted if necessary (please refer to the eyemate-Reader IFU for details).
- GAT adjustment must not be performed at IOPs> 21mmHg (measured by GAT).
- GAT adjustment must always be performed with caution, in particular in the case of the eyes with extreme anatomical/biomechanical deviations.
- Note: GAT is recommended as a reference for eyemate®-IO measurements. Nevertheless, GAT adjustment must always be performed with caution, taking into account the fact that GAT is an indirect IOP measurement method and is known to be prone to error. GAT error is particularly prominent in the case of eyes with extreme anatomical/biomechanical deviations or at IOPs>21 mmHg.
- If the discrepancy between IOPs obtained by eyemate®-IO system and GAT method is above 5mmHg, calibration is required as specified in the eyemate-Reader IFU.
- Following eyemate®-IO re-calibration using GAT, an IOP measurement must be obtained and compared to GAT measurement to confirm that re-calibration was successful (please refer to eyemate-Reader IFU).

⚠ IOP monitoring and glaucoma management

- The eyemate®-IO system is not intended to replace the current diagnostic methods for IOP measurements. The measured IOP values must be verified by standard method (e.g. Goldmann applanation tonometry) prior to prescription of IOP management therapies.

⚠ eyemate®-IO interactions with medical procedures and therapies

- Do not use high energy ultrasound in the vicinity of the implant.
- Do not use diathermy in the vicinity of the implant.
- Do not use therapeutic ionizing radiation in the vicinity of the implant.
- Avoid hyperbaric therapy.
- Do not expose the implant to direct laser energy impact.
- **MRI:** The eyemate®-IO implant is safe in MRI field strength of up to 3T (please refer to the following section for details)
- **GDD:** Alternative implantation technique may be required. Glaucoma drainage devices (GDD) are unlikely to interfere with the eyemate®-IO implant if they are placed such that there is no physical contact between the two devices.
- **Ocular surgeries and therapies:** Take special care during ocular surgeries and therapies. The eyemate®-IO implant may be damaged due to mechanical or high energy impact.

3.4 MRI safety information

Non-clinical testing demonstrated that eyemate®-IO is MR Conditional. A patient with this device can be scanned safely immediately after implantation under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the eyemate®-IO produced the following temperature rise during MRI performed for 15 min of scanning (i.e., per pulse sequence) in 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.6˚C

Therefore, the MRI-related heating experiments for the eyemate®-IO at 3 Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6˚C

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the eyemate®-IO. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5 mm relative to the size and shape of the eyemate®-IO.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	103mm^2	24mm^2	140mm^2	38mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

4 Possible complications and adverse events

Complications may occur due to excessive surgical manipulation of the eye while implanting the eyemate®-IO device. These complications are also associated with standard cataract surgeries. However, implantation of the additional device may increase their likelihood and/or severity. Nevertheless, these adverse events could be minimized or eliminated by surgeon training as well as following all of the instructions regarding implant handing and surgical procedure. Possible adverse events are:

- Increased intraocular pressure due to pigment dispersion, incomplete removal of the viscoelastic material during surgery or use of corticosteroids following the surgery. Increased IOP due to narrowing of the anterior chamber angle is unlikely.
- Anterior chamber inflammation and, in extreme cases, fibrin reaction
- Iris prolapse due to floppy iris syndrome or excessive/incorrect surgical manipulation
- Corneal/macular/conjunctival edema
- Unequal pupils
- Trans-illumination defects and, in severe cases, “glare” due to iris pigment dispersion
- Damage to corneal endothelial layer/corneal endothelial cell loss due to excessive or incorrect surgical manipulation. In severe cases this may lead to corneal opacification.
- Foreign body sensation
- Temporary visual impairment as a secondary effect caused by the adverse events described above.

In most cases, the complications that may arise following eyemate®-IO implantation are expected to be temporary and manageable by standard of care.

Please brief the patient on the possible complications and adverse events before the implantation.

5 Pre-Implantation process

Determination of the implant size

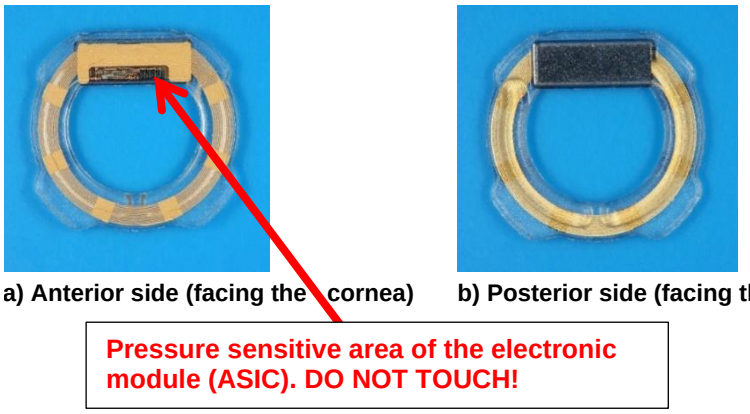
The recommended eyemate®-IO implant size will be determined based on the horizontal White-to-White (WTW) measured by the IOL Master (manual measurement obtained with the cursor). This measurement shall be confirmed using an UBM (ultrasound biomicroscope). At least three WTW measurements will be taken and the average calculated. The average in mm will then be used for fitting the eyemate®-IO implant size (Table 1). The surgeon may re-assess this selection if intraoperative findings prescribe a different implant size. In borderline cases, it is recommended to choose the smaller option. WTW measurements outside the specified ranges are not suitable for eyemate®-IO implantation.

⚠ **Warning:** Eyes with ciliary sulcus diameter of <11.2mm or >12.4mm (obtained by any standard measurement method) are not suitable for eyemate®-IO implantation.

Table 1: Recommendation for eyemate®-IO implant size

WTW Measurement (mm)	Recommended eyemate®-IO implant size (mm)
11.2 to 11.59	11.3
11.6 to 11.99	11.7
12.0 to 12.4	12.1

Figure 2: Anterior and posterior view of the eyemate®-IO implant



a) Anterior side (facing the cornea) **b) Posterior side (facing the lens)**

Pre-implantation check

The functionality of the eyemate®-IO implant must be tested prior to implantation. Implant the device only if a pre-implantation measurement within the range of ±2mmHg is obtained.

⚠ **Warning:** Do not implant the eyemate®-IO if pre-implantation check has not been successfully performed.

6 Implantation

The implantation of the eyemate®-IO implant is performed using the Medicel ACCUJECT™ EM-IO 1.1 Injector. For detailed description of the implantation procedure please refer to the *Medicel ACCUJECT™ EM-IO 1.1 Injector IFU*.

It is recommended to have 2 implants of each size available during implantation.

⚠ **Warning:** Implantation is only to be performed using Medicel injector in accordance with the *Medicel ACCUJECT™ EM-IO 1.1 Injector IFU*.

7 Explantation

Note:	It is not necessary to explant an eyemate®-IO implant which is either non-functional or is known to function incorrectly. The malfunctioning device may safely remain in the eye.

The eyemate®-IO implant can be explanted at any time when medically indicated. The following steps describe the explantation procedure:

- Create a corneal incision of approximately 3.5 mm with an appropriate instrument. The corneal incision should be angled such that it is not perpendicular to the limbus, but rather at an approximately 20° angle. Assuming the ASIC of the implant is in the 12 o'clock location, the corneal incision is made at 6 o'clock position.
- Create two paracenteses in 10 and 2 o'clock positions for inserting micro-instruments.
- Intracameral ophthalmic viscoelastic material injection in used to stabilize the anterior chamber and also behind the iris to spread the sulcus. This ensures better access to the implant and avoids iris abrasion during the explantation.
- Hold the eyemate®-IO implant with toothed micro-forceps (which is inserted through one paracentesis) at 6 o'clock position and move it slightly forward to ensure the micro-coil does not touch the iris or the capsular bag.
- Carefully cut the micro-coil with suitable micro-scissors, where it is visible and most accessible. Ideally, only one radial cut needs to be performed.
- The easiest point for cutting the micro-coil is shown in figure 3. This is the thinnest section of the coil. However, if the implant ASIC is not at 12 o'clock position and it is unpractical to make the corneal incisions at locations described above, consider cutting the implant micro-coil at either side of the ring, in between the two haptics. Avoid cutting the haptic region and never attempt to cut the ASIC.
- Feed one end of the now open ring through the corneal incision and using forceps extrude the rest of the implant through this incision in a rotational manner.
- While rotating the implant out of the eye, gently depress the part of the implant that is still inside the eye with an appropriate spatula (which is inserted through a paracentesis), in order to avoid corneal endothelial touch.
- Remove the viscoelastic material and, if necessary, close the corneal incision with sutures following standard procedure.
- Please return the explanted eyemate®-IO device to the manufacturer.

⚠ **Warning:** The implant cannot be cut at the ASIC region.

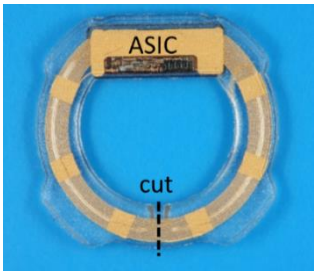


Figure 3: Proposed location for cutting the micro-coil.

8 How supplied

Packaging

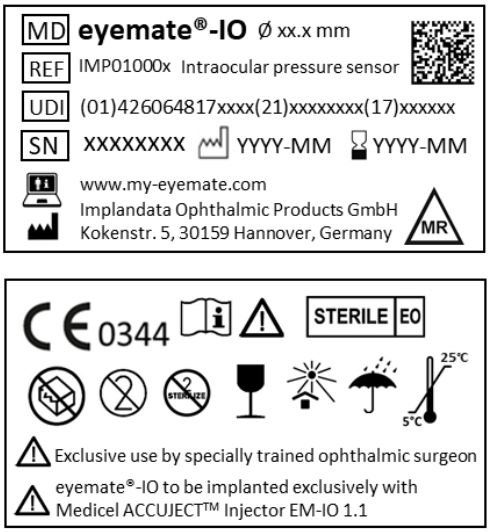
The eyemate®-IO implant is supplied EtO sterilized in a multilayer packaging.

Storage and handling

To minimize contamination and to provide maximum protection, store the eyemate®-IO implant in its original packaging at room temperature in a dry area protected from direct sunlight.

Under proper storage conditions, the eyemate®-IO implant can be used until the expiry date identified on the label, provided that the package was not opened or damaged. The maximum shelf life is 1 year.

eyemate®-IO labels and description of symbols



Sales packaging labels

Sterile packaging label

The implant has a unique serial number, which is shown on the label and can be read out telemetrically (the implant surface is too small to bear the serial number).

Description of symbols			
MD	Medical device		Consult instructions for use
SN	Serial number		Caution
UDI	Unique device identification (in human-readable format and 2D data matrix)	MR	MRI conditional (please refer to the MRI safety information provided in this IFU)
	Date of manufacture	STERILE EO	Sterilized using ethylene oxide
	Use-by date	2 STERILE	Do not re-sterilize

	Temperature limit		Do not re-use
	Do not use if package is damaged and consult “instructions for use”		Keep dry
	Keep away from sunlight		Manufacturer
	Handle with care	CE 0344	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.
	Patient information website (manufacturer’s website)	REF	Catalogue number

9 Implant Card

Please fill out the enclosed Implant Card according to the instructions provided in its information leaflet. The Implant Card is to be provided to the implanted patient.

10 eyemate®-IO implant specifications and environmental conditions

Parameter	Specification
Available implant sizes	∅ 11.3 mm (IMP010001) ∅ 11.7 mm (IMP010002) ∅ 12.1 mm (IMP010003)
Implant thickness	0.5-0.9mm (all implant sizes)
Encapsulation material (the only material in contact with the patient)	Silicone (MED-6820, Nusil)
Total weight of the implants (11.3mm, 11.7mm and 12.1mm)	52 mg, 55 mg and 63 mg
Surface area of the implants (11.3mm, 11.7mm and 12.1mm)	141 mm^2, 144 mm^2, 162 mm^2
Operating temperature range	Min. 31° C; Typ. 35° C; Max. 40° C
Operating pressure range	800-1150 hPa
Carrier frequency	13.56 MHz
Measurement accuracy	±2 mmHg
Maximum readout range (distance of electromagnetic field)	40 mm
Storage temperature	5°C to 25°C
Storage pressure	<2000 hPa absolute pressure

11 Manufacturer

Implandata Ophthalmic Products GmbH
Kokenstrasse 5
D-30159 Hannover, Germany
Phone: +49 (0) 511 22042580
Fax: +49 (0) 511 22042589
www.my-eyemate.com
General inquires: info@implandata.com
Technical issues: service@implandata.com
Reporting complaints/serious incidents: complaint@implandata.com

12 Troubleshooting

In case of any issues or technical questions, please contact the manufacturer. Manufacturer’s contact details are provided in section 11.

13 Device disposal

Please return the explanted or damaged implants to the manufacturer for disposal. Please place the implant in physiological saline inside a sealed container. Manufacturer’s contact details are provided in section 11.

14 Medication

The following is the perioperative treatment recommendation for eyemate®-IO implant:

30 days prior to surgery (advisable, but not mandatory)

Modification of the glaucoma therapy:

If necessary, stop prostaglandins (advisable, but not mandatory)

One day prior to surgery

Treatment in the ward:

5x Polyspectran® (Polymyxin B + Neomycin + Gramicidin) -–eye drops

4x Ocuflur® (Flurbiprofen) -–eye drops

On the surgery day

Treatment in the ward:

1x Mydrum® (Tropicamid) -–eye drops

2x Neosynephrine POS® 10 % (Phenylephrinhydrochlorid) -–eye drops

1x Polyspectran® (Polymyxin B + Neomycin + Gramicidin) -–eye drops

1x Ocuflur® (Flurbiprofen) -–eye drops

Treatment in the OR:

1x Ocuflur® (Flurbiprofen) -–eye drops

1x Neosynephrine-POS® 10 % (Phenylephrinhydrochlorid) -–eye drops

1x Mydrum® (Tropicamid) -–eye drops

1x Novesine® (Oxybuprocainhydrochlorid) -–eye drops

Immediately postoperative:

Isopto-Max® (Dexamethason + Neomycinsulfate + Polymyxin-B-sulfate) -–eye ointment

Protective eyepatch

Aftercare

Treatment in the ward:

5x Isopto-Max® (Dexamethason + Neomycinsulfate + Polymyxin-B-sulfate) -–eye drops

5x Acular® (Ketorolac) -–eye drops

Isopto-Max® (Dexamethason + Neomycinsulfate + Polymyxin-B-sulfate) -–eye ointment at night

NaCl 5% - eye ointment at night

Protective eyepatch at night (also daily, if necessary; in the case of monocular vision use transparent eyepatch)

Treatment after discharge:

5x Isopto-Max ® (Dexamethason + Neomycinsulfate + Polymyxin-B-sulfate) -–eye drops

4x Acular® (Ketorolac) -–eye drops

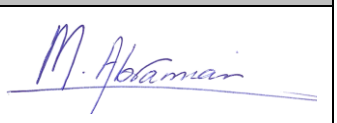
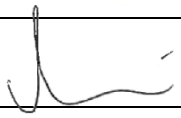
Isopto-Max® (Dexamethason + Neomycinsulfate + Polymyxin-B-sulfate) -–eye ointment at night (avoid prostaglandin treatment until postoperative inflammation is eliminated)

From day 6 post-operative:

3x Isopto-Dex® (Dexamethason) -–eye drops

4x Acular® (Ketorolac) -–eye drops (for approximately 3 months)

Approval

	Name / Function	Date	Signature
Prepared by:	Dr. Miganoosh Abramian/Sr. Engineer R&D and Regulatory Affairs	31.08.2021	
Reviewed by:	Dr. Wouter van Drunen/Sr. Engineer R&D and Clinical Trials	31.08.2021	
Reviewed by:	Stefan Meyer/CTO and Head of R&D	31.08.2021	
Reviewed by:	Prof. Dr. med. Kaweh Mansouri/Chief Medical Officer	31.08.2021	
Reviewed by:	Max Ostermeier/ Head of Marketing and Sales	31.08.2021	
Approved by:	Max Ostermeier/ General Manager	31.08.2021	
Released by:	Elke Haßel/ Head of QM&RA	31.08.2021	

History

Version	Release Date DD. Month YYYY	Description of Change	Reason of change	Author
I	28.03.2017	MR Information was added	MR compatibility information was needed in the IFU	M. Abramian
J	28.04.2017	List of recommended medication was added	DEKRA requirement	M. Abramian
K	02.05.2017	Storage temperature was updated (maximum temperature was changes from 40°C to 25°C to be consistent with the packaging validation data)	Inconsistency in IFU and validation test	M. Abramian
L	15.02.2018	Add Axis length >26mm as contraindications (section 3). Add information of GAT adjustment with IOP >21mmHg, and with eyes of extreme anatomic/biomechanical deviations to the cautions (Section 5).	Device Explantation in Rostock	S. Meyer

		Add caution in section 7. Change from "it will not function correctly" to "it may cause iris abrasion" to Implantation process in section 7.		
M	11.10.2018	Change of the incision length, injector article number and denotation	New injector	W. van Drunen
N	19.08.2019	Change from EYEMATE-IO to eyemate®. Add website www.implandata.com to the contact address. Add "this instructions for use can be downloaded on the website www.implandata.com"	eyemate is registered mark; MDR requirement on manufacturer IFU and website	H. Sun
MDR DRAFT 1 [Upon release, the new revision numbering system will be used: 15.0 instead of Rev.O]	Not to be released before MDR CE certification	General updates and implementation of MDR 2017/745 requirements (Annex I, Chapter III). Implantation process has been moved to the Injector IFU, to have it together with the injector loading process. The warning messages and safety information are grouped based on different topics to make them more user-friendly. The following warning message was added in accordance with MDR 2017/745 Annex I Chapter III, 23.4 (p): "Re-injection or re-processing may result in deterioration of the material and cause tissue injury and/or adversely affect the device functionality." The following warning message was added in accordance with MDR 2017/745 Annex I Chapter III, 23.4 (z): "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…" Update of the layout to be consistent with the reader device IFU.	Initial MDR submission	M. Abramian
MDR DRAFT 2	Not to be released before MDR CE certification (16.12.2020)	-implant labels were corrected -link to EUDAMED was added. -specifications table was updated. -generic names of the medications were added.	Updates in response to MDR submission package review by the notified body	M. Abramian
15.0	See above	The DRAFT, which has been approved by the notified body (MDR CE certification on 17.06.2021), is now being released. The following changes were made: -The email address for reporting serious incidents has been changed to complaint@implandata.com - the label image and the description of symbols table is updated based on the revised label specifications document. -CE year of authorization is added.	MDR CE certification	M. Abramian