This instructions for use can be downloaded on the website www.implandata.com

Device Regulation: AIMDD 90/385/EEC

The eyemate®-IO intraocular pressure sensor is a CE marked (CE 0344, 2017) active implantable medical device (AIMD). Together with the Mesograph reader device, it is intended as a diagnostic system for users to measure the intraocular pressure (IOP).

The Mesograph reader device and its accessories (REA100000) 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.

These Instructions for Use (IFU) only describe the handling and use of the eyemate®-IO implant. Please refer to the *eyemate®-IO Injector 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 eyemate®-IO system.

The eyemate®-IO implant is supplied EtO sterilized.

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

Table of Contents

1. Description of eyemate®-IO pressure sensing implant

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

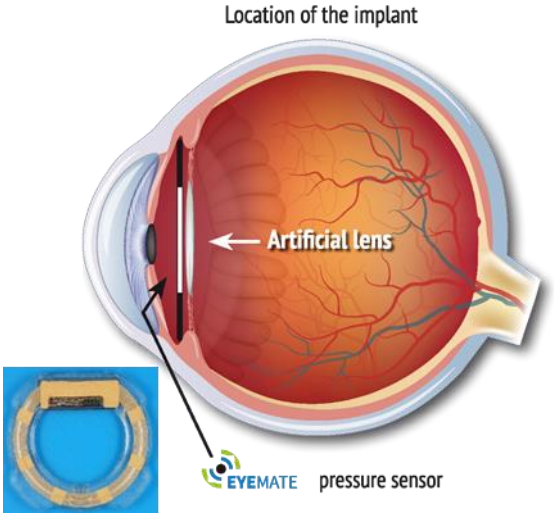


Figure 1: location of the eyemate®-IO implant

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 Mesograph reading device in front of the eye (Please refer to the *Mesograph 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 7 for information regarding the implant size choice.

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.

2. Indications

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.

3. 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 than 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

4. ⚠ Warnings

- Only specially trained, qualified and experienced ophthalmic surgeons may perform the implantation procedure. Contact the manufacturer for surgeon training details.
- Observe the contraindications.
- eyemate®-IO pressure sensing device is only to be implanted using the Medicel ACCUJECT Injector EM-IO 1.1.
- eyemate®-IO implant is delivered sterile and is a single-use device. It must not be reused, re-injected, re-conditioned or re-sterilized.
- 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.
- 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.
- Consult this IFU before eyemate®-IO implantation, as non-conformity may result in a hazardous situation for the patient or damage to the implant.
- 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 (GAT)) prior to prescription of IOP management therapies.

5. ⚠ Cautions

- 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.
- The complete eyemate®-IO set (which includes two implants of each size, two reader devices and two injectors) must be available during the implantation procedure.
- Each reader device within an implantation kit is specifically programmed to operate with the eyemate®-IO implants in that kit. Do not mix implants or reader devices from different kits.
- 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 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.
- Do not inject the eyemate®-IO implant too fast as it may result in tissue abrasion by the quickly unfolding implant.
- 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.
- Implant operates correctly within the absolute pressure range of 800-1150 hPa. Therefore, at altitudes above 1700 meters reliable measurements cannot be obtained.
- Avoid activities such as scuba-diving. Absolute pressure beyond 2000 hPa (10 meters underwater) will permanently damage the implant.
- **MRI:** The eyemate®-IO implant is safe in MRI field strength of up to 3T (please refer to section 9 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.

- 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 GAT (the average of 3 eyemate®-IO measurements are compared to one GAT measurement), and adjusted if necessary (please refer to the *Mesograph 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 eyemate®-IO and GAT measurement methods is above 5mmHg or if no measurements can be obtained by the eyemate®-IO system, contact the manufacturer.
- 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 *Mesograph IFU*).

6. 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 medication.

7. Implantation

Determination of the implant size

The recommended eyemate®-IO implant size will be determined based on the horizontal White-to-White (WTW) measurement obtained with the IOL Master. This measurement shall be confirmed using an UBM (ultrasound biomicroscope). At least three WTW measurements will be taken and the

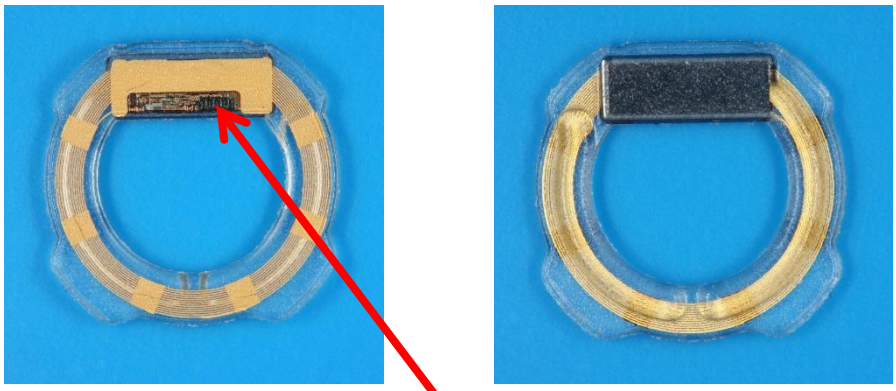
average calculated. The average in mm will then be used for fitting the eyemate®-IO implant size (Table 1). The surgeon may re-assess this selection if intraoperative findings prescribe a different implant size. In borderline cases, it is recommended to choose the smaller option. WTW measurements outside the specified ranges are not suitable for eyemate®-IO implantation.

⚠ **Caution:** Eyes with sulcus diameter of <11.2mm or >12.4mm (obtained by any 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)**

Implantation process

⚠ **Caution:** Only use smooth forceps for handling the implant and never touch the ASIC, in order to avoid permanent damage to the implant.

- 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 3.2mm clear corneal or corneo-scleral incision is recommended.
- Use cohesive ophthalmic viscoelastic material (Sodium Hyaluronate) to stabilize the anterior chamber
- To verify the eyemate®-IO functionality prior to implantation, an IOP measurement is performed through the sterile pack. The reading must be within ±2mmHg.
- Very gently remove the eyemate®-IO implant from the packaging.

- Load the implant into the injector as described in the *eyemate®-IO Injector IFU.*
- 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 (DO NOT USE methylcellulose based viscoelastic) in order to provide the optimum space for the implant.
- 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 device.
- 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 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.
- Following implantation, return the unused implants in their original packaging as well as any used or damaged implants to the manufacturer.

8. 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 pressure sensing device 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.
- Return the explanted eyemate®-IO device to the manufacturer.

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

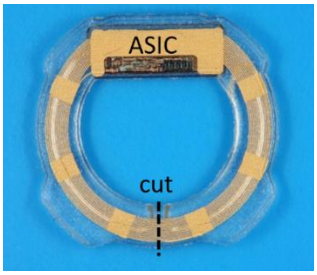


Figure 3. Proposed location for cutting the micro-coil.

9. How supplied

Packaging

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

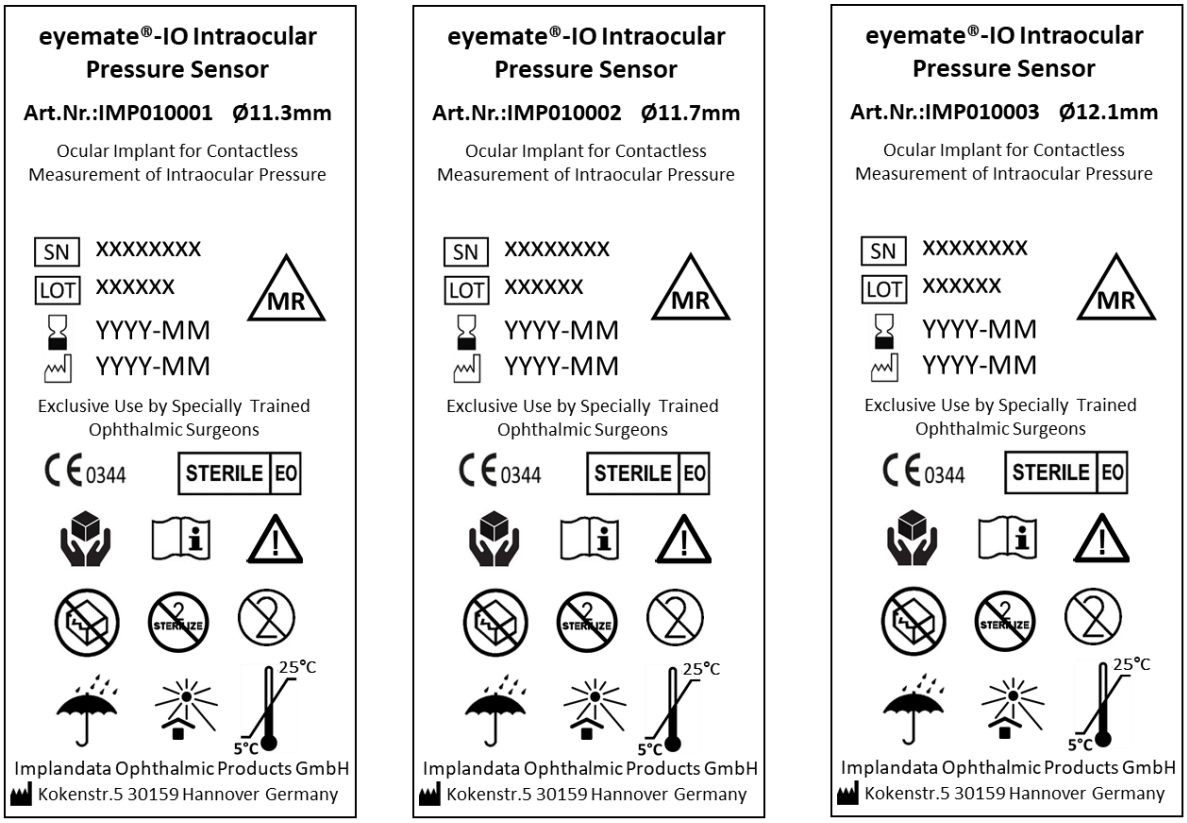
Storage and handling

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.

Label

Figure 4: eyemate®-IO implant 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).

SN	Serial number		Consult instructions for use
LOT	Batch number		Caution
	Manufacturing date	STERILE EO	Sterilized using ethylene oxide

	Expiry date		Do not re-sterilize
	Temperature limitation		Single use
	Do not use if the sterile barrier system is damaged		Keep dry
	Avoid exposure to direct sun		Manufacturer
	Handle with care	CE 0344	Device is manufactured in compliance with the requirements of the directive for active implantable medical devices 90/385/EEC

The device also bears an MR conditional label.

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	103mm2	24mm2	140mm2	38mm2

Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

10. eyemate®-IO implant specifications

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)
Operating temperature range	Min. 31° C; Typ. 35° C; Max. 40° C
Operating pressure range	800-1150 hPa
Carrier frequency	13.56 MHz
Measurement resolution	1 mmHg
Maximum readout range (distance of electromagnetic field)	40 mm
Storage temperature	5°C to 25°C
Storage pressure	<2000 hPa absolute pressure
Weight (11.3mm, 11.7mm and 12.1mm implants)	52 mg, 55mg and 63mg

11. Troubleshooting

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

Implandata Ophthalmic Products GmbH
Kokenstrasse 5
D-30159 Hannover, Germany
Phone: +49 (0) 511 22042580
Fax: +49 (0) 511 22042589
www.implandata.com
info@implandata.com

12. 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 - eye drops
4x Ocuflur - eye drops

On the surgery day
Treatment in the ward:
1x Mydrum - eye drops
2x Neosynephrine 10 % - eye drops

1x Polyspectran - eye drops
1x Ocuflur - eye drops

Treatment in the OR:
1x Ocuflur - eye drops
1x Neosynephrine 10 % - eye drops
1x Mydrum - eye drops
1x Novesine - eye drops

Immediately postoperative:
Isopto-Max - eye ointment
Protective eyepatch

Aftercare
Treatment in the ward:
5x Isopto-Max - eye drops
5x Acular - eye drops
Isopto-Max - 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 - eye drops
4x Acular - eye drops
Isopto-Max - eye ointment at night (avoid prostaglandin treatment until postoperative inflammation is eliminated)

From day 6 post-operative:
3x Isopto-Dex - eye drops
4x Acular - eye drops (for approximately 3 months)