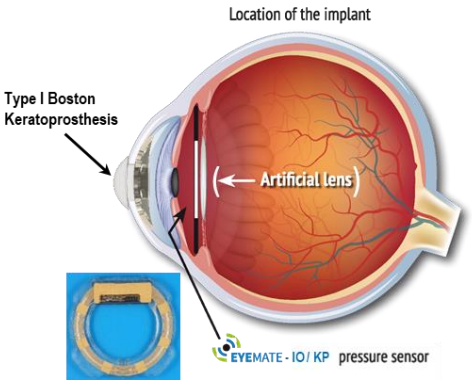
Implandata Ophthalmic Products GmbH

EYEMATE®-IO/KP Implant

Instructions for Use

Rev. D / 2018-11



CE 0344

Device Regulation: AIMDD 90/385/EEC

The EYEMATE®-IO/KP intraocular pressure sensor is a CE marked (CE 0344, year of authorization) 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 (REA100013) provide wireless power and data transmission and is used for obtaining IOP measurements from the EYEMATE®-IO/KP implant.

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

The EYEMATE®-IO/KP implant is supplied EtO sterilized.

Warning: Read this IFU carefully and follow the instructions!

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1. Description of EYEMATE®-IO/KP pressure sensing implant

The EYEMATE®-IO/KP pressure sensing device is a permanent AIMD, intended to be implanted in the posterior chamber of an aphakic or pseudophakic human eye at patients undergoing Boston Keratoprosthesis Type I procedure.

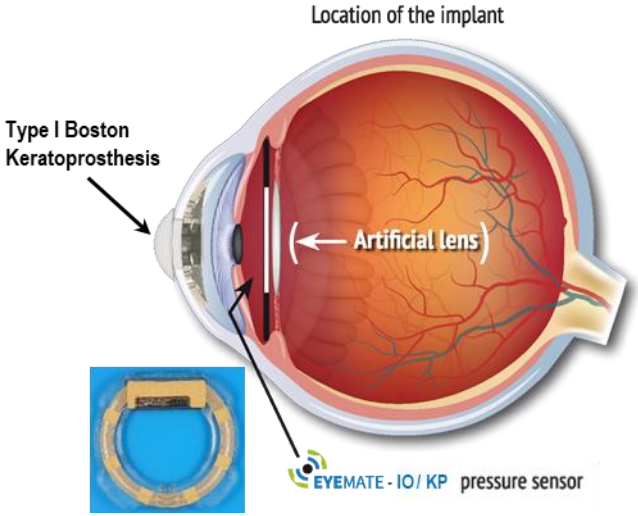


Figure 1: Location of the EYEMATE®-IO/KP implant

The EYEMATE®-IO/KP 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/KP implant is available in three sizes: 11.3mm (IMP130001), 11.7mm (IMP130002) and 12.1mm (IMP130003) in diameter. Please refer to section 7 for information regarding the implant size choice.

Each reader device within an implantation kit is specifically programmed to operate with the EYEMATE®-IO/KP implants in that kit. Do not mix implants or reader devices from different kits.

The life-time of the EYEMATE®-IO/KP 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/KP intraocular pressure sensor is an AIMD to be permanently implanted in patients indicated for the Boston-Keratoprosthesis Type I (BI-KPro) implantation.

3. Contraindications

Warning: Observe the contraindications!

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

- Patients <18 years of age
- Eyes with a ciliary sulcus diameter or equivalent measurement smaller than 11.2mm or larger than 12.4mm
- Axis length <22mm or >26mm
- Any known intolerance or hypersensitivity to topical anesthetics, mydriatics, or silicone (component of the device)
- AIMDs in the head/neck region

- Severe surgical complication prior to Keratoprosthesis placement

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/KP implant is delivered sterile and is a single-use device. It must not be reused, 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. Be especially careful during the (high energy) Nd:YAG retroprosthetic membrane removal procedure.
- Consult this IFU before EYEMATE®-IO/KP implantation, as non-conformity may result in a hazardous situation for the patient or damage to the implant.
- Therapeutic decision should not be made on EYEMATE-IO/KP measurements alone, existing other diagnostic and anamnesis methods and the past medical history of the patients shall be considered as well.

5. ⚠ Cautions

- Handle the implant with care.
- The functionality of the EYEMATE®-IO/KP 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/KP 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.
- It is crucial to ensure that the pupil is fully dilated during the EYEMATE®-IO/KP implantation.
- A pupil diameter of ≤9mm is not appropriate for EYEMATE®-IO/KP implantation.
- 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 resulting in a potentially significant increase of IOP, such as scuba-diving. Absolute pressure beyond 2000 hPa (10 meters underwater) will permanently damage the implant.
- **MRI:** The EYEMATE®-IO/KP implant is safe in MRI field strength of up to 3T (please refer to section 9 for details)
- **GDD:** Glaucoma drainage devices (GDD) are unlikely to interfere with the EYEMATE®-IO/KP 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/KP 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/KP implant must be confirmed by an experienced and qualified

specialist using finger palpation (the average of 3 EYEMATE®-IO/KP measurements are compared to one palpation measurement), and adjusted if necessary (please refer to the *Mesograph IFU* for details).

- IOP adjustment must always be performed with caution, in particular in the case of the eyes with extreme anatomical/biomechanical deviations.
  Note: Finger palpation is recommended as a reference for EYEMATE®-IO/KP measurements. Nevertheless, IOP adjustment must always be performed with caution, taking into account the fact that finger palpation is an indirect IOP measurement method and is known to be prone to (user) variability.
- If the discrepancy between EYEMATE®-IO/KP and finger palpation measurement methods is above 5mmHg or if no measurements can be obtained by the EYEMATE®-IO/KP system, contact the manufacturer.
- Following EYEMATE®-IO/KP re-calibration using finger palpation, an IOP measurement must be obtained and compared to finger palpation 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/KP device. These complications are also associated with the standard Boston-Keratoprosthesis surgery. However, implantation of the additional device may increase their likelihood and/or severity. To avoid unnecessary risk, all surgeons should undergo the Implandata surgeon training. Possible adverse events are:

- Retroprosthetic membrane (RPM) formation
- Increased intraocular pressure
- Glaucoma progression
- Choriodal effusion / detachment / neovascularization
- Conjunctival inflammation
- Corneal epithelium defect / infiltrates / necrosis / melt
- Cystoid macular edema
- Endophthalmitis
- Epiretinal membrane
- Hypotony
- Keratitis
- Posterior capsule opacification
- Proliferative diabetic retinopathy
- Prosthesis extrusion
- Retinal detachment / necrosis / tear
- Suprachoroidal hemorrhage
- Uveitis
- Vitreous hemorrhage
- Vitritis

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

7. Implantation

Determination of the implant size

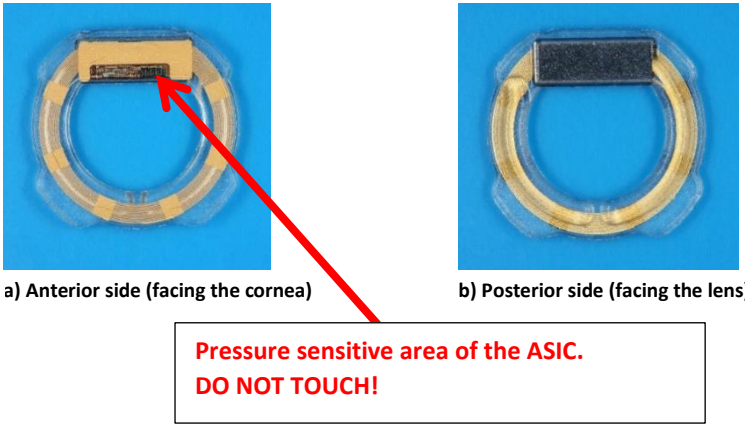
The recommended EYEMATE®-IO/KP implant size will be determined based on the ciliary sulcus diameter or equivalent measurement. The diameter in mm will then be used for fitting the EYEMATE®-IO/KP implant size (Table 1). The surgeon may re-assess this selection if intraoperative findings prescribe a different implant size. In borderline cases, it is recommended to choose the smaller option. Diameter measurements outside the specified ranges are not suitable for EYEMATE®-IO/KP implantation.

Caution: Eyes with ciliary sulcus diameter of <11.2mm or >12.4mm (obtained by any measurement method) are not suitable for EYEMATE®-IO/KP implantation.

Table 1: Recommendation for EYEMATE®-IO/KP implant size

Sulcus Diameter Measurement (mm)	Recommended EYEMATE®-IO/KP 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/KP 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.

Assure that the complete EYEMATE®-IO/KP set (which includes two implants of each size and two reader devices) must be available during the implantation procedure.

The surgical approach will involve a typical trephination of adequate size of the central cornea of the recipient. Phakic subjects will undergo cataract extraction by an open sky approach allowing nuclear and cortical removal. If the subject is pseudophakic, the IOL will be dealt with according to the site's customary keratoprosthesis implantation procedure. A posterior chamber IOL implanted in the capsular bag can remain in the eye. The anatomical situation will be inspected in all cases to assess whether adequate support exists for sulcus implantation of the EYEMATE®-IO/KP.

Following cataract extraction or IOL explantation, viscoelastic material will be placed under the iris to allow adequate exposure of the sulcus space.

In subjects with adequate capsular support, the sensor device will be placed in the sulcus space by grasping the sensor's silicone sleeve at approximately the 3 and 9 o'clock positions with 1 or 2 implantation forceps and gently sliding it into the sulcus space.

In subjects in whom capsular support is inadequate, the EYEMATE®-IO/KP implant will be sutured transsclerally to the sclera. This is performed by placing an 8-O Gortex suture or 9-O prolene on CIF-4 needles around the antenna loop at the 2 and 7 o'clock positions and suturing the device to the sclera using an ab interno technique.

Once the EYEMATE®-IO/KP implant is adequately positioned, the Boston keratoprosthesis will be sutured in place by standard method.

Following implantation, return the unused implants in their original packaging as well as any used or damaged implants to the manufacturer.

After the implantation process, the standard aftercare / postoperative treatment for BI-KPro patients should be utilized. If a Nd:YAG treatment for RPM is performed, the performance of the EYEMATE®-IO/KP implant has to be closely monitored.

8. Explantation

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

The EYEMATE®-IO/KP pressure sensing device can be explanted at any time when medically indicated. The following steps describe the explantation procedure:

- Free the corneal natural graft-host junction (no need to disassemble the BI-KPro)
- Place viscoelastic device to stabilize the anterior chamber
- Transect the EYEMATE-IO/KP implant at the microcoil area with appropriate scissors (e.g. Vannas scissors)
- Extrude one end of the transected implant through the wound with forceps and gently pull the rest of the implant out of the eye.
- Replace graft, and re-suture.
- Return the explanted EYEMATE®-IO/KP device to the manufacturer.

If visualization does not permit the use of the above explantation technique, the surgeon must follow an alternative approach based on the individual situation.

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

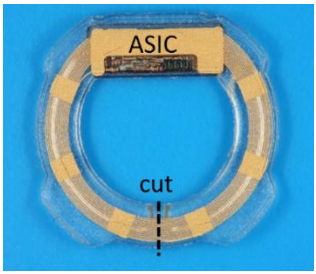


Figure 3. Proposed location for cutting the micro-coil.

9. How supplied

Packaging

The EYEMATE®-IO/KP implant is supplied EtO sterilized in a multilayer packaging.

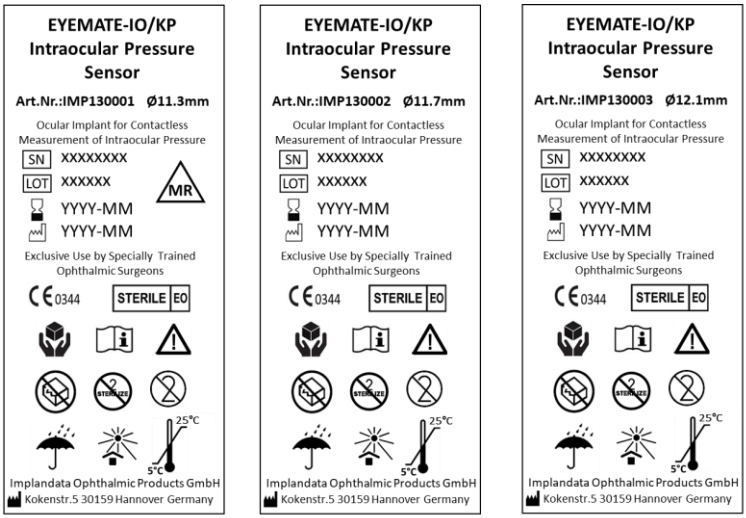
Storage and handling

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

Under proper storage conditions, the EYEMATE®-IO/KP 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/KP 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	2 STERILE	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/KP 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/KP 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/KP 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/KP. 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/KP.

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

10. EYEMATE®-IO/KP implant specifications

Parameter	Specification
Available implant sizes	∅ 11.3 mm (IMP130001) ∅ 11.7 mm (IMP130002) ∅ 12.1 mm (IMP130003)
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:

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