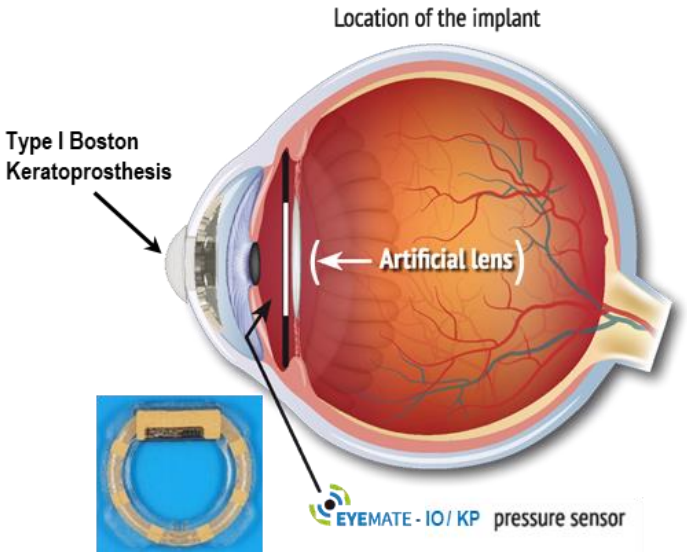
eyemate®-IO/KP Implant

Instructions for use

Version 2024-06 (en)



CE 0344

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 The complaint form can be downloaded from: http://infocenter.my-eyemate.com/
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 summary of safety and clinical performance (SSCP) for eyemate®-IO/KP is available in the European database on medical devices (EUDAMED) and it is linked to the basic UDI-DI: 426064817IMP137G.
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/KP intraocular pressure sensor (IMP130001, IMP130002 and IMP130003) 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) provides wireless power and data transmission and is used for obtaining IOP measurements from the eyemate®-IO/KP implant.

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

1.1 About this instruction for use

These Instructions for Use (IFU) only describe the handling and use of the eyemate®-IO/KP implant.

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/KP system.

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	Actie Implantable Medical Device
ASIC	Application specific integrated circuit (the electronic module of the implant)
EtO	Ethylene Oxide
IFU	Instructions for use
IOL	Intraocular lens
IOP	Intraocular pressure
WTW	White-to-white

2 Description of eyemate®-IO/KP pressure sensing implant

The eyemate®-IO/KP intraocular pressure sensor is a permanent AIMD, intended to be implanted in the posterior chamber of an aphakic or pseudophakic eye (**Figure 1**) in patients undergoing Boston Keratoprosthesis Type I procedure.

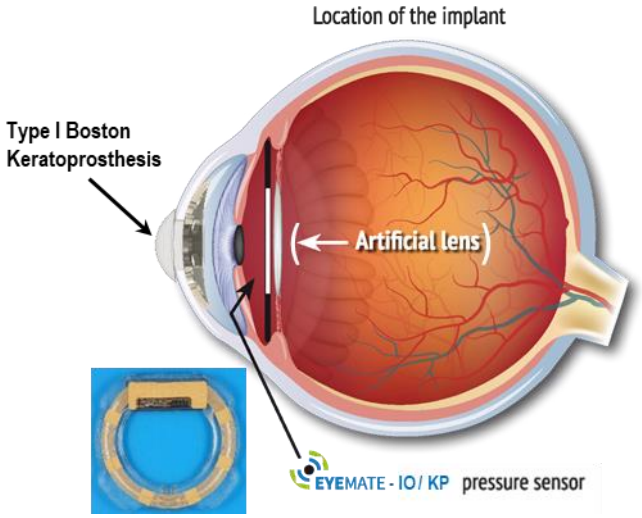


Figure 1: Location of the eyemate®-IO/KP implant

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 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/KP implant is available in three sizes: 11.3 mm (IMP130001), 11.7 mm (IMP130002) and 12.1 mm (IMP130003) in diameter. Please refer to **section 5** for information regarding the implant size selection.

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.

Intended user and use environment

eyemate®-IO/KP 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/KP intraocular pressure sensor is a permanent AIMD intended to be implanted in the posterior chamber of an aphakic or pseudophakic eye in patients indicated for Boston-Keratoprosthesis Type I (BI-KPro) implantation.

3.2 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 11.2 mm or larger than 12.4 mm
- Axis length < 22 mm or > 26 mm
- Any known intolerance or hypersensitivity to topical anesthetics, mydriatics, or silicone (component of the device)
- Active implantable medical devices (AIMDs) in the head/neck region
- Severe surgical complication prior to Keratoprosthesis placement

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/KP 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/KP implantation, as non-conformity may result in a hazardous situation for the patient or damage to the implant.
- eyemate®-IO/KP implant is delivered sterile and is a single-use device. It must not be reused, re-conditioned or re-sterilized. Re-processing or re-use 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.
- 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 ±2 mmHg is obtained.
- Handle the implant with care.
- Do not deform or alter the configuration of the implant.
- 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 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/KP implant to come into contact with any chemicals other than standard ophthalmic viscoelastic materials, sterile isotonic solution or sterile physiological saline.
- Do not implant the eyemate®-IO/KP if complications occur during the surgical procedure.
- It is crucial to ensure that the pupil is fully dilated during the eyemate®-IO/KP implantation.
- A pupil diameter of ≤9 mm is not appropriate for eyemate®-IO/KP implantation.

⚠ 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 involving significant increase in ambient pressure, such as scuba-diving. Absolute pressure beyond 2000 hPa (10 meters underwater) will permanently damage the implant.

⚠ eyemate®-IO/KP calibration

- 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 *eyemate®-Reader 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 5 mmHg 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 the *eyemate®-Reader IFU*).

⚠ IOP monitoring and glaucoma management

- 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.

⚠ eyemate®-IO/KP 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. Be especially careful during the (high energy) Nd:YAG retroprosthetic membrane photodisruption procedure. If a Nd:YAG treatment for RPM is performed, the performance of the eyemate®-IO/KP implant must be closely monitored.
- **MRI:** The eyemate®-IO/KP 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/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.

3.4 MRI safety information

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

4 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 vitreo-retinopathy (PVR)
- 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.

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

5 Implantation

Determination of the implant size

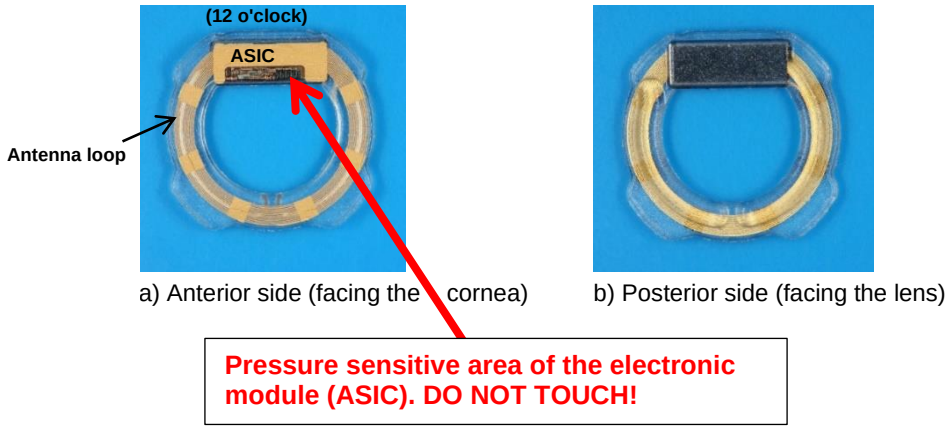
The recommended eyemate®-IO/KP implant size will be determined based on the ciliary sulcus diameter or equivalent measurement. The diameter in mm will then be used for fitting the eyemate®-IO/KP implant size (**Table 1**). The surgeon may re-assess this selection if intraoperative findings prescribe 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.

WARNING!

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

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

WTW 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



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

Figure 2: eyemate®-IO/KP implant

eyemate®-IO/KP Implant orientation in the eye

When implanted, the anterior surface of the eyemate®-IO/KP is facing the cornea. If implanted backwards, the device must be explanted. Do not attempt to flip the implant inside the eye.

It is preferable to have the ASIC in the superior position in the eye. However, if this is not the case, do not attempt to rotate the implant within the sulcus.

Pre-implantation check

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 ±2 mmHg is obtained.

WARNING!

Do not implant the eyemate®-IO/KP if pre-implantation check has not been successfully performed.

Implantation process

WARNING!

Only use smooth forceps for handling the implant and never touch the ASIC (**Figure 2**), in order to avoid permanent damage to the implant.

It is recommended to have implants of each size and backups available during the implantation procedure.

The surgical approach involves a typical trephination of adequate size of the central cornea of the recipient. Phakic subjects undergo cataract extraction by an open sky approach, allowing nuclear and cortical removal. If the subject is pseudophakic, the IOL is 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 must 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 is placed under the iris to allow adequate exposure of the sulcus space.

In subjects with adequate capsular support, the eyemate®-IO/KP is placed in the sulcus space by grasping the sensor's antenna loop at approximately the 3 and 9 o'clock positions with two implantation forceps and gently sliding it into the sulcus space. **DO NOT TOUCH THE ASIC**.

In subjects in whom capsular support is inadequate, the eyemate®-IO/KP implant is sutured trans-sclerally. 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. **DO NOT PIERCE THE IMPLANT**.

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

Following implantation, please 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.

6 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 antenna loop 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.

WARNING!

The implant cannot be cut at the ASIC region.

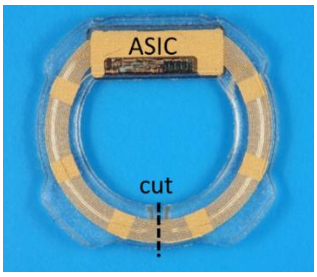


Figure 2: Proposed location for cutting the antenna loop.

7 How supplied

Packaging

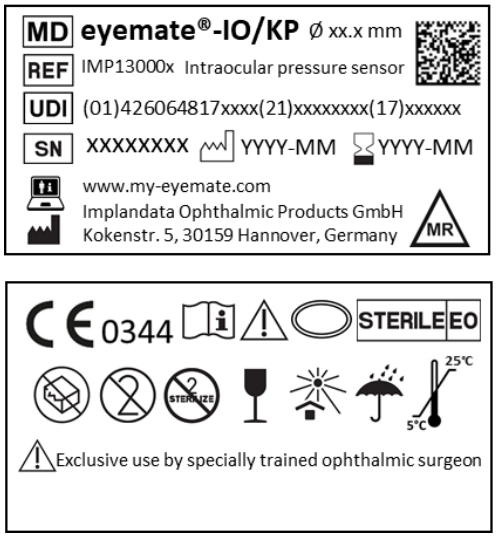
The eyemate®-IO/KP implant is supplied EtO sterilized in a multilayer packaging.

Storage and handling

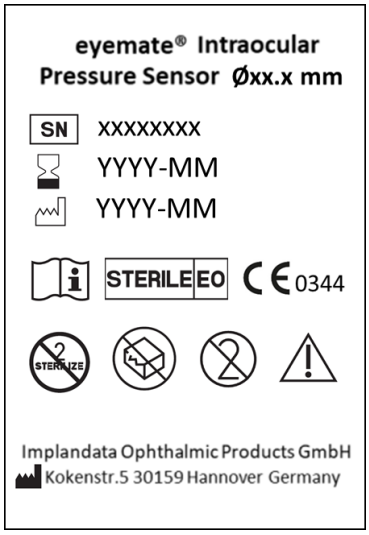
To minimize contamination and to provide maximum protection, store the eyemate®-IO/KP implant in its original packaging at room temperature in a dry area protected from direct sunlight.

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.

eyemate®-IO/KP 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			
REF	Catalogue number		Caution
	Consult instructions for use		Date of manufacture
	Do not re-sterilize		Do not re-use
	Do not use if package is damaged and consult “instructions for use”		Double sterile barrier system

Description of symbols			
	Handle with care		Keep away from sunlight
	Keep dry		Manufacturer
	Medical device		MRI conditional (please refer to the MRI safety information provided in this IFU)
	Serial number		Sterilized using ethylene oxide
	Temperature limit		Unique device identification (in human-readable format and 2D data matrix)
	Use-by date		Patient information website (manufacturer's website)
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.		

8 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.

9 eyemate®-IO/KP environmental conditions and implant specifications

Parameters and materials	
Available implant sizes	∅ 11.3 mm (IMP130001) ∅ 11.7 mm (IMP130002) ∅ 12.1 mm (IMP130003)
Implant thickness	0.5-0.9 mm (all implant sizes)
Encapsulation material (the only material in contact with the patient)	Silicone (MED-6820, Nusil)
Total weight of the implants (11.3 mm, 11.7 mm and 12.1 mm)	52 mg, 55 mg and 63 mg
Surface area of the implants (11.3 mm, 11.7 mm and 12.1 mm)	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

10 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

11 Troubleshooting

In case of any issues or technical questions, please contact the manufacturer. Manufacturer's contact details are provided in **section 10**.

12 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 10**.