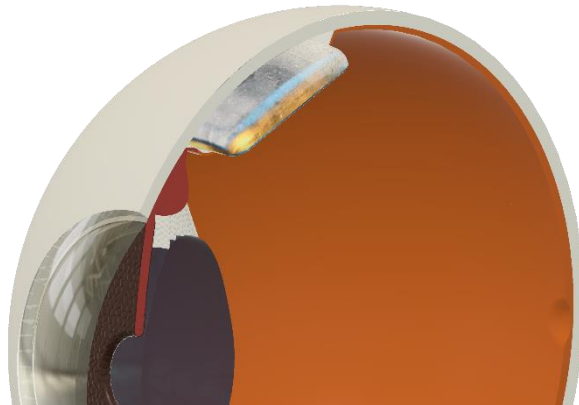


eyemate[®]-SC Implant

Instruction for use

Version 10.0 / 2021-08



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<http://infocenter.my-eyemate.com/>





Version of this document V10.0/2021-08

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®-SC** is available in the European database on medical devices (EUDAMED) and it is linked to the basic UDI-DI: 426064817IMP217F.
<https://ec.europa.eu/tools/eudamed>

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

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1 General Information

The eyemate®-SC intraocular pressure sensor (IMP210001) is a CE marked (CE₀₃₄₄, 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®-SC implant.

For implantation of the eyemate®-SC pressure sensing device, eyemate®-SC Silicone Paddings provided by Implants (SUG210001) is used with standard implantation forceps.

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

The eyemate®-SC silicone paddings are single-use and are supplied EtO sterilized.

1.1 About this instruction for use

These Instructions for Use (IFU) only describe the handling and use of the eyemate®-SC implant prior and during the surgical implantation of the device.

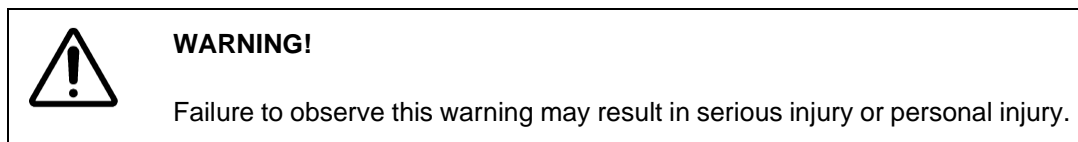
Please refer to the eyemate®-Reader IFU for further instructions on the use of the system.

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®-SC system.



Warning: Read this IFU carefully and follow the instructions!

1.2 Symbols used in this instruction for use



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
IOP	Intraocular pressure
NPGS	Non-penetrating glaucoma surgery
OVD	ocular viscoelastic device

2 Description of the eyemate®-SC pressure sensing implant

The eyemate®-SC pressure sensing device is a permanent AIMD, intended to be implanted in the suprachoroidal space of the human eye, in combination with non-penetrating glaucoma surgery (NPGS).

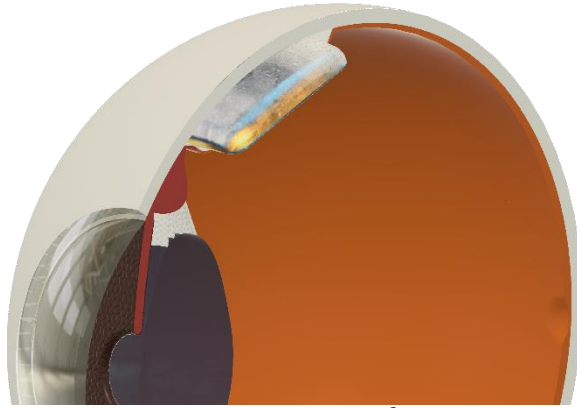


Figure 1: Location of the eyemate®-SC implant (dimensions: 7.5 mm x 3.5 mm)

The eyemate®-SC system directly measures the IOP within the vitreous cavity, unaffected by the choroidal and retinal layers, which is equal to the pressure within the anterior chamber. The system provides digitized IOP readings in mmHg and 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*).

Please note that the system is not intended to replace the current diagnostic methods for IOP measurements nor is it 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®-SC implant is available in one size (IMP210001).

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

Intended user and use environment

The eyemate®-SC is only to be implanted by specially trained, qualified and experienced ophthalmic surgeons in *Healthcare Facility Environment*. 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®-SC intraocular pressure sensor is an AIMD to be permanently implanted in the suprachoroidal space in patients indicated for non-penetrating glaucoma surgery (NPGS).

3.2 Contraindications



Warning: Observe the contraindications!

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

1. Age <18 years
 - Contraindications for a non-penetrating glaucoma surgery
 - Neovascular glaucoma, primary and secondary angle closure glaucoma
 - Myopia (>-6 dpt) or hypermetropia (> +4 dpt)
 - Axis length < 22 mm or > 26 mm
 - Acute retinal detachment
 - Uncontrolled Diabetes Mellitus (DM) with manifestation of moderate to severe non-proliferative diabetic Retinopathy (DR) or proliferative DR.
 - Existence of another active implantable medical device in the head/neck region
 - Difficulties or complications during NPGS procedure or implantation of eyemate®-SC sensor, as assessed by surgeon (e.g. perforation of trabeculo-descement's membrane; excessive aqueous filtration through TDM leading to shallow anterior chamber; hypotony; excessive bleeding; choroidal detachment)
 - Other medical reasons that prohibit the placement of the eyemate®-SC implant.

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®-SC implant and surgical considerations

- Only specially trained, qualified and experienced ophthalmic surgeons may perform the implantation procedure. Contact the manufacturer for surgeon training details.
- The duration of the NPGS plus sensor implantation may be longer than NPGS alone.
- Observe the contraindications.
- Consult this IFU before eyemate®-SC implantation, as non-conformity may result in a hazardous situation for the patient or damage to the implant.

- Do not implant the eyemate®-SC device if complications occur during the course of the non-penetrating Glaucoma surgery prior to placement of the implant, including but not limited to perforation of trabeculo-descement's membrane, excessive aqueous filtration through TDM leading to shallow anterior chamber, hypotony, excessive bleeding and choroidal detachment.
- To ensure wireless communication of the eyemate®-Reader with the eyemate®-SC implant is possible, in particular in patients with extreme facial features, it is recommended to place the eyemate®-SC implant as anterior and temporal as possible. The expected position of the implant is within 3 mm behind the limbus towards the equator of the eye.
- eyemate®-SC implant is delivered sterile and is a single-use device. It must not be reused, 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.
- Two eyemate®-SC implants and two sets of eyemate®-SC Silicone Paddings shall be available during the implantation, to ensure accessibility of back-ups.
- 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®-SC implant must be tested prior to implantation. Implant the device only if a pre-implantation measurement within the range of $\pm 2\text{mmHg}$ is obtained.
- 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.
- Handle the implant with care.
- Handle the implant only with atraumatic surgical instruments, do not touch with gloves.
- eyemate®-SC pressure sensing device is only to be implanted using the eyemate®-SC Silicone Paddings provided by the manufacturer (SUG210001) together with standard surgical forceps.
- Do not allow the eyemate®-SC implant to come into contact with any chemicals other than standard ophthalmic viscoelastic materials during the surgical procedure.
- Do not use methylcellulose based viscoelastic.
- Do not deform or alter the configuration of the implant.
- Never touch the pressure sensitive area of the ASIC to avoid permanent damage.
- If silicone oil is used in conjunction with the eyemate®-SC implant, the performance of the sensor needs to be closely monitored.
- Do not soak the implant in any solution other than a sterile isotonic solution or sterile physiological saline.
- Do not insert the eyemate®-SC implant too fast or forcefully as it may result in tissue damage or choroidal bleeding/rupture.
- The implant is to be placed with the "pressure sensing side" facing the vitreous body.
- Following implantation, in particular in early post-operative phase, instruct the patient to avoid eye-rubbing.

 **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®-SC calibration

- Following implantation, following any ocular procedure and at least once a year the correct function of the *eyemate*®-SC implant must be confirmed by an experienced and qualified specialist using GAT (the average of 3 *eyemate*®-SC 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*®-SC 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*®-SC and GAT measurement methods is above 5mmHg, calibration is required as specified in the *eyemate*®-Reader IFU.
- Following *eyemate*®-SC 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*®-SC 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®-SC 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.
- **GDD:** If implantation of glaucoma drainage devices (GDD) should be necessary in any of the *eyemate*®-SC patients, implantation will not be facilitated in the same quadrant as the NPGS/*eyemate*®-SC site.
- **MRI:** The *eyemate*®-SC implant is safe in MRI field strength of up to 3T (please refer to the following section for details)
- **Ocular surgeries and therapies:** Take special care during ocular surgeries and therapies. The *eyemate*®-SC implant may be damaged due to mechanical or high energy impact.

3.4 MRI safety information

Non-clinical testing on the technically similar eyemate®-IO device demonstrated that eyemate®-SC device 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® implant 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® implant 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® implant. 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® implant.

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 surgical manipulation of the eye while implanting the eyemate®-SC device. These complications are also associated with standard non-penetrating glaucoma surgery. However, implantation of the additional device may increase their likelihood and/or severity. Nevertheless, these adverse events will be minimized or eliminated by surgeon training as well as following all of the instructions regarding implant handling and surgical procedure. Possible adverse events are:

- Perforation/Rupture of the trabeculo-descement's membrane (TDM)
- Anterior chamber inflammation
- Hypotony
- Shallow anterior chamber
- Suprachoroidal hemorrhage
- Choroidal detachment
- Retinal detachment
- Hyphema
- Blebitis
- Iris incarceration in TDM
- Temporary visual impairment as a secondary effect caused by the adverse events described above.

In most cases, the complications that may arise following eyemate®-SC 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

5.1 Pre-implantation check

The functionality of the eyemate®-SC 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®-SC if pre-implantation check has not been successfully performed.

5.2 Non-penetrating glaucoma surgery (NPGS) and preparation for implantation

The NPGS procedure will be performed in the surgeon's usual technique. While the surgical approach for the NPGS will be various, all procedures involve the following scleral preparation:

- A fornix based conjunctival peritomy is performed over 2 to 3 clock hours.
- A superficial scleral flap is created measuring about 5 mm by 5 mm.
- A deep scleral flap of varying size (4x4 mm or smaller, according to the surgeon's preference) is then created within the borders of the superficial flap dissecting down to within 10-50 microns of the choroid.
- The remainder of procedure is performed, according to the surgeon's habitual technique.
- Prior to closure of the superficial flap the eyemate®-SC is implanted, as described below.

5.3 eyemate®-SC Implantation



Warnings:

- Do not implant eyemate®-SC if complications occur during NPGS or implantation.
- Do not use methylcellulose based viscoelastic.
- The implant is to be placed with the "pressure sensing side" facing the vitreous body.
- Only use smooth forceps with the supplied eyemate®-SC Silicone Paddings (SUG020001) for handling the implant.
- Never touch the pressure sensitive area of the ASIC to avoid permanent damage.

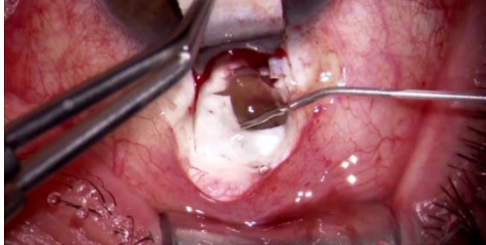
To ensure wireless communication of the eyemate®-Reader with the eyemate®-SC implant is possible, in particular in patients with extreme facial features, it is recommended to place the eyemate®-SC implant as anterior and temporal as possible. The expected position of the implant is within 3 mm behind the limbus towards the equator of the eye.

The following steps describe the implantation procedure of the eyemate®-SC device:

1. For an uncomplicated insertion of the eyemate®-SC implant, the scleral window, which is referred to as "deep scleral flap" or "scleral lake", needs to be at least 3.2 mm to 3.5 mm wide (maximum 4x4 mm). If the NPGS procedure was performed with a narrower scleral opening, the width of the flap needs to be enlarged or an additional small incision next to the flap needs to be performed to ensure a scleral opening of at least 3.2 mm.



2. A hyaluronic acid-based ocular viscoelastic device (e.g., Healon OVD, Abbott Medical Optics Inc.) is used to separate the sclera from the choroid and additionally serves as a safeguard against injuries of the surrounding tissue. Viscoelastics based on hydroxypropyl methylcellulose (HMPC) or other synthetic or semi-synthetic alternatives to hyaluronic acids must not be used, as this material may not fully dissolve in the postoperative phase and may cause inflammation.



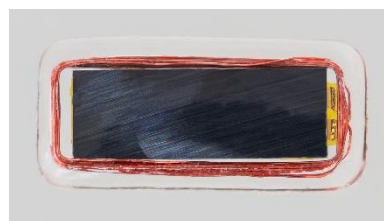
3. Standard surgical forceps (not provided) covered with the eyemate®-SC Silicone Paddings (SUG210001) facilitate the implantation and protect the eyemate®-SC implant from damage through mechanical irritation. Unpadded surgical forceps and instruments must not be used for handling the implants, as these may cause damage.



4. The implant is to be placed with the “pressure sensing side” of the sensor facing the vitreous body. Thus, the orientation of the ASIC (figure below) is important and must be checked prior to implantation. During handling of the implant, it is critical not to contact the pressure sensitive area of the electronic module.



Anterior view (side towards the vitreous humor)

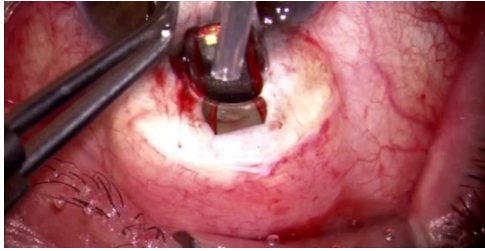


Posterior view (side towards the sclera)

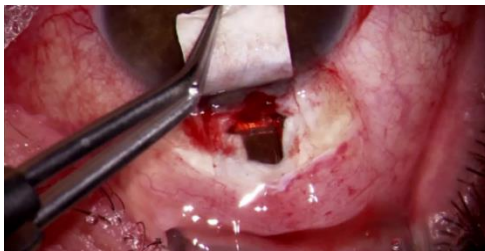
Pressure sensitive area of the electronic module (ASIC). DO NOT TOUCH!

5. In the event that the implant becomes too slippery to be handled after contact with OVD, both the implant and the silicone paddings can be flushed with a sterile isotonic solution or sterile physiological saline to wash off the viscoelastic material.

6. Gently insert the eyemate®-SC implant through the scleral opening into the suprachoroidal space using the above-mentioned silicone padded implantation forceps. It is important to avoid a forcible implantation process because excessive mechanical load on the eyemate®-SC device may cause damage to both tissues surrounding the implant and the implant itself.



7. The implant is partially inserted into the suprachoroidal space through the posterior part of the scleral lake and partially left within this area as a space maintainer, as shown below.



8. After insertion of the eyemate®-SC implant, the superficial scleral flap and the conjunctiva are closed and sutured.

An alternative surgical approach is the insertion of the eyemate®-SC sensor in the suprachoroidal space through a scleral incision that is not parallel to the limbus but in an angle of e.g., 45° directly adjacent, in line and posterior to the deep scleral lake.

6 Explantation

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

For explantation, a scleral incision (e.g. with a crescent knife) of 4.5-5 mm needs to be performed above or at least next to the short side of the implant. The incision should be placed above the pars plana and should provide a fully opened scleral incision to ensure a safe explantation procedure.

Alternatively, the scleral flap may be re-opened, as done for complete revisions of NPGS.

Before removing the eyemate®-SC implant, hyaluronic acid-based viscoelastic (e.g. Healon OVD, Abbott Medical Optics Inc.) has to be inserted in the suprachoroidal space to ensure a complete separation of the sclera and choroid. Toothed forceps may be used to grab the implant and pull it out of the suprachoroidal cavity. If desired, the implant may be replaced by a new device in the same procedure.

The scleral incision should be sealed after explantation by at least one suture. In cases where the device has been removed through the scleral flap, the flap is to be closed in the standard way.

The explanted device is to be returned to the manufacturer (please refer to section 12).

7 How supplied

Packaging

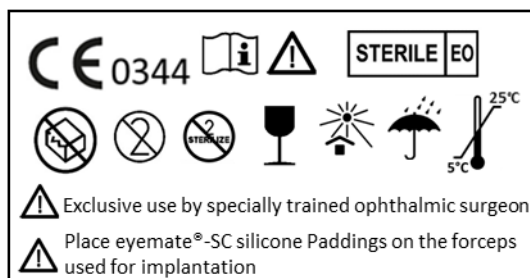
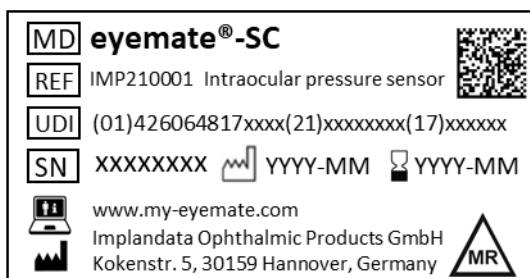
The eyemate®-SC implant is supplied EtO sterilized in a multilayer packaging.

Storage and handling

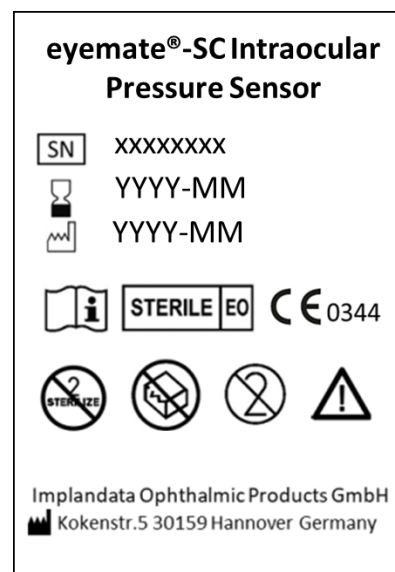
To minimize contamination and to provide maximum protection, store the eyemate®-SC implant in its original packaging at room temperature in a dry area protected from direct sunlight.

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

eyemate®-SC 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			
	Medical device		Consult instructions for use
	Serial number		Caution
	Unique device identification (in human-readable format and 2D data matrix)		MRI conditional (please refer to the MRI safety information provided in this IFU)
	Date of manufacture		Sterilized using ethylene oxide

	Use by date		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		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)		Catalogue number

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®-SC implant specifications and environmental conditions**

Parameter	Specification
Minimum lifetime	10 years
Implant dimensions	7.5 mm x 3.5 mm
Implant thickness	1.29 mm (center), 0.85 mm (edges)
Encapsulation material (the implant is fully encapsulated, and this is the only material in contact with the patient)	Silicone (MED-6820, Nusil)
Weight of the implant	41 mg
Surface area of the implant	61 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)	30 mm
Storage temperature	5°C to 25°C
Storage pressure	<2000 hPa absolute pressure

10 Manufacturer

Implandata Ophthalmic Products GmbH

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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 eyemate®-SC implants to the manufacturer. Please place the implant in physiological saline inside a sealed container. Manufacturer's contact details are provided in section 10.

The eyemate®-SC Silicone Paddings are to be disposed of in regular surgical waste.

13 Recommended Medication Regimen

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

Modification of the glaucoma therapy:

If necessary, stop prostaglandins

On day of surgery

Treatment in the ward:

1x antibiotic eye drops (e.g. Polyspectran® (Polymyxin B + Neomycin + Gramicidin))

Topical Povidon-Iod Solution

Pilocarpine (1-2%) eye drops as required

Treatment in the OR:

1x local anesthetic eye drops (e.g. Oxybuprocaine/Benoxinate)

Acetylcholin or Carbachol solution as needed

Immediately postoperative:

Steroid-antibiotic combination ointment or drop (e.g., Isopto-Max® (Neomycin + Dexamethason + Polymyxin B sulfate) or Trobadex® (Tobramycin + Dexamethasone))

Protective eyepatch

Postoperative follow-up:

Treatment after discharge:

Avoid prostaglandin treatment until postoperative inflammation is eliminated

Artificial tears are recommended

Protective eyepatch at night for one week (also daily, if necessary. In case of monocular vision: use transparent eyepatch)

Non-steroidal anti-inflammatory or corticosteroid (surgeon's discretion) and antibiotic eye drops (e.g., Trobadex® (Tobramycin + Dexamethasone)) 6x daily, degressive reduction over 1 month or frequency at surgeon's discretion

Minimum 4 weeks non-steroidal anti-inflammatory or corticosteroid eye drops or ointment and minimum 2 weeks antibiotic eye drops or ointment

Month 2:

Non-steroidal anti-inflammatory drops (e.g., Acular® (Ketorolac) or Nevanac® (Nepafenac)), 4x daily or frequency at surgeon's discretion