INSTRUCTIONS FOR USE

eyePlate glaucoma drainage implant

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DEVICE DESCRIPTION

The eyePlate is an artificial non-valved drainage device that drains aqueous humor via a tube from the anterior chamber of the eye to an episcleral plate. The eyePlate is designed to allow an alternate pathway for aqueous humor in order to lower intraocular pressure to physiological levels. The entire device is made out of medical grade silicone. The plate has a convex shape with radius of 15mm to match the curvature of the ocular globe. The device exists in four versions:
- eyePlate-200 with plate area of 200mm^2 and tube of 0.63mm external diameter and 0.3mm internal diameter.
- eyePlate-200s with plate areas of 200mm^2 and tube of 0.467mm external diameter and 0.18mm internal diameter.
- eyePlate-300 with plate area of 300mm^2 and tube of 0.63mm external diameter and 0.3mm internal diameter.
- eyePlate-300s with plate areas of 300mm^2 and tube of 0.467mm external diameter and 0.18mm internal diameter.

The plate features two fixation holes for scleral attachment and three fenestrations for limiting the bleb's volume after implantation. The tube has a length of 28-30mm.

Model	Surface area	Tube diameter (outer/inner)	Plate length	Plate width
eyePlate-200	200 mm^2	0.63/0.3 mm	16.8mm	14.5mm
eyePlate-200s	200 mm^2	0.467/0.18 mm	16.8mm	14.5mm
eyePlate-300	300 mm^2	0.63/0.3 mm	18.9mm	18.5mm
eyePlate-300s	300 mm^2	0.467/0.18 mm	18.9mm	18.5mm

INDICATIONS FOR USE / INTENDED USE

The eyePlate is intended to lower intraocular pressure in glaucoma adults where medically controlled glaucoma or filtering surgery have failed or are likely to fail, such as, but not limited to, neovascular glaucoma, aphakic/pseudophakic glaucoma, uveitic glaucoma, congenital glaucoma, etc.

INTENDED POPULATION

The eyePlate is indicated for adults suffering from glaucoma where medical and/or conventional surgical treatments have failed.

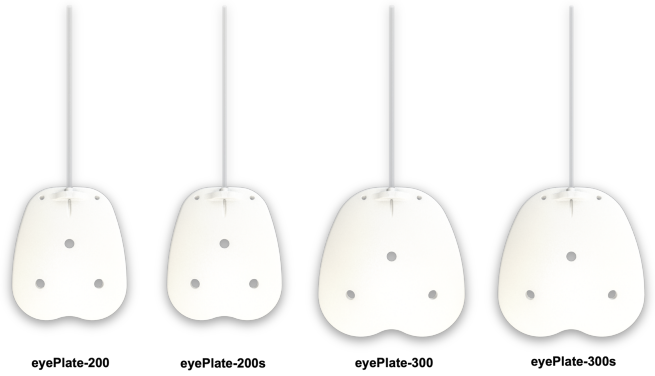

Figure 1: Illustration of all eyePlate models: eyePlate-200, eyePlate-200s, eyePlate-300 and eyePlate-300s

EXPECTED CLINICAL BENEFITS

The primary clinical benefit of the eyePlate is that it can lower the IOP of the patient. The eyePlate in standalone configuration can lower the IOP of the patients efficiently. Evidence of such benefit is demonstrated in a study by F. Ahmed et al (2024), which reported an IOP reduction of 67% at 12 months. When combined to an eyeWatch implant, the eyePlate reported a 50% IOP reduction at 1 year (Swiss clinical study (*NCT02554214*)). The mean IOP in that study was reduced from 24.5mmHg to 12.2mmHg after 1 year.

In stand alone configuration, the eyePlate-300 lowers the use of anti-glaucoma medications of at least 79% at 1 year (Ahmed et al. 2024). When combined with an eyeWatch implant, in the Swiss and United Kingdom clinical studies (*NCT03210571*), the use anti-glaucoma medications in patients decreased by 72% and 65% respectively. In the Swiss clinical study, patients which were taking in average 2.1 medications before eyeWatch surgery, reduced their use in average to 0.8 after 1 year. For the United Kingdom study, the anti-glaucoma medication use was reduced from 2.0 to 1.1 after 1 year.

The summary of safety and clinical performance will be available on the EUDAMED database upon notify body approval on the following webpage: ec.europa.eu/tools/eudamed. It will also be available upon request.

EXPOSED MATERIALS

Implant materials to which patients are exposed: MED-4860 (Medical grade long-term implantable silicone) mixed with MED-4800-1 (white medical grade long-term implantable silicone masterbatch) ≃ 480 mm^2 for eyePlate-200/200s and 680 mm^2 for eyePlate-300/300s, Nusil MED-4750 (medical grade long-term implantable biocompatible silicone) up to 85mm^2 (depending on length of the residual tube), MED-2000 (Medical grade long-term implantable silicone glue < 5 mm^2.

CONTRAINDICATIONS

Conjunctivitis, corneal ulcers, endophthalmitis, orbital cellulitis, bacteremia or septicemia, active scleritis, active uveitis, scleral buckle, rectus muscle surgery.

WARNINGS

The eyePlate should not be used if sterility is compromised. The device is intended for single use only. To prevent cross-contaminations and/or ineffective treatment, the eyePlate shall not be re-used and/or re-sterilized.

COMPLICATIONS AND RESIDUAL RISKS

The main complications (side effects) that may happen during or after the implantation of the eyePlate are similar to those encountered after any type of filtering surgery and might comprise (not an exhaustive list): suprachoroidal hemorrhage ; hyphema; choroidal effusion/detachment; flat/shallow anterior chamber; conjunctival erosion; wound leak; corneal edema; bleb encapsulation, dysesthesia; cystoid macular edema; aqueous misdirection; hypotony maculopathy; vitreous hemorrhage; retinal detachment; endophthalmitis or blebitis; iritis; tube erosion; tube-cornea touch; tube obstruction by blood clot, iris or vitreous; cataract progression; motility disorder; diplopia; malignant glaucoma; no light perception.
Residual risks include conjunctival erosion, wound leak, choroidal effusion and hyphema.

DIRECTIONS FOR USE

1. Examine the implant prior to implantation for proper size, model and expiration date. 2. Open the blister carefully and remove the implant in a sterile environment. 3. The implant can become electrostatically charged upon opening the package. Examine the implant to ensure that particles are not present on it. Rinse implant in sterile saline, if required.

IMPLANTATION

STANDARD IMPLANTATION:
A high-level of surgical skills is required for the implantation of artificial drainage devices. Meticulous surgery and postoperative care are required. The surgeon should have observed and/or assisted in numerous artificial glaucoma drainage devices implantations prior to implanting an eyePlate implant. The implant is commonly implanted in the supero temporal or the infero nasal quadrant.

1.A fornix based conjunctival flap is used to dissect the conjunctiva and tenon's capsula from the sclera.
2.The end plate is positioned between the rectus muscles and is attached to the sclera at about 6-8 mm posterior to the limbus using 8-0 Prolene sutures through the fixation holes of the eyePlate. The sutures should be tight in order to prevent any plate movement, but not excessively, as the user should be able to rotate the knots into the fixation holes in order to prevent conjunctival erosion.
3.The tube is cut with an anterior bevel so that a 2 to 3mm segment will extend into the anterior chamber from the site of the limbal entry.
4.A 23-gauge needle (for eyePlate-200 and eyePlate-300) or a 25-gauge needle (for eyePlate-200s and eyePlate-300s) is used to make the entry incision into the anterior chamber. The incision should be performed at the posterior limbus parallel to the iris plane.
5.The tube should be obstructed with a temporary plug 4-0 or 5-0 Prolene suture (for eyePlate-200 and eyePlate-300) or 5-0 or 6-0 Prolene suture (for eyePlate-200s and eyePlate-300s) inserted in the lumen and/or ligated with a biodegradable ligature (7-0 or 8-0 Vicryl).

It is recommended that the limbal portion of the tube is covered with a scleral/corneal patch graft. The graft is sutured in place with interrupted sutures. The conjunctiva is closed with mattress sutures and a running closure for radial relaxing incisions.

IMPLANTATION WITH EYEWATCH IMPLANT:
The eyePlate can also be used in combination with an eyeWatch implant. The eyePlate should be placed and sutured before the implantation of the eyeWatch implant.

1. After a proper opening of the conjunctiva (fornix or limbus based), the eyePlate is placed under the conjunctiva and sutured at 10-12 mm from the limbus.
2. Place the eyeWatch following eyeWatch implant's recommendations.
3. After placing the eyeWatch, trim the tube of the eyePlate to the right length, the tube is then connected to the rear end connector of the eyeWatch implant (Outlet).
4. Finalize the procedure as described in surgical procedures steps of the eyeWatch implant.

For more information on the implantation procedure of the eyeWatch implant, please refer to the instructions for use of the eyeWatch device. In case of implantation with an eyeWatch implant, it is not recommended to perform any tube ligation or obstruction technique on the eyePlate.

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HOW SUPPLIED/EXPIRATION DATE
Each eyePlate implant is supplied sterile, within a double sterile blister pack. The implants are sterilized using X-ray irradiation. Sterility is guaranteed unless the blister is damaged or otherwise compromised. Expiration date is indicated on the outside of the box. The implant should not be used after the indicated expiration date. The implant should be stored in a dry environment and at room temperature (15°C-25°C).

PRECAUTIONS
The opening of the packaging and the handling of the device shall obey the Good Clinical Practice in surgery. The rules to keep the implant sterile throughout the entire surgery shall be strictly followed. The eyePlate should not be used if sterility is compromised and should be replaced by a new one. The eyePlate is intended for single use only. To prevent cross-contaminations and/or ineffective treatment, the eyePlate shall not be re-used and/or re-sterilized.

EXPECTED LIFETIME
The eyePlate implant is intended for long-term use. The physician should monitor the patient postoperatively for proper maintenance of IOP as performance may change over time. If IOP is not adequately maintained, the physician should consider appropriate additional therapy to maintain the target IOP.

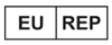
USER PROFILE
The eyePlate is intended to be used by surgeons who have experience with drainage devices in glaucoma surgery.

DISPOSAL OF THE DEVICE
In the event of damaged/unsterile or defective explanted implant, contact Rheon Medical SA for product return policy. Return the implant with proper identification and reason for return. Label return as biohazard.

IMPLANT CARD
An implant card is supplied in the implant packaging. This card should be given to the patient with instructions to keep as a permanent record of the implant and to show the card to any eye care practitioner seen in the future.

REPORTING
Adverse reactions and/or potentially sight-threatening complications that may be reasonably regarded as product related and that were not previously expected in nature, severity or incidence must be reported to competent authority of the member state in which the user and/or patient is established and to Rheon Medical SA. This information is requested from all surgeons in order to document potential long-term effects of glaucoma implants. Potential problems may be related to a specific lot of products or may be indicative of long-term problems associated with these types of products. Report any product related adverse event to: info@rheonmedical.com.

SYMBOLS USED ON PACKAGING:

Symbol	Meaning	Symbol	Meaning
	Consult Instructions for Use		Catalogue number
	European authorized representative		Medical Device
	Sterilized Using Irradiation		MR safe
	Double sterile barrier		Use by [YYYY-MM-DD]
	Do Not Reuse		Manufacturing date [YYYY-MM-DD]
	Do Not Resterilize		Manufacturer
	Do Not Use if Damaged Package		Keep dry
SN	Serial Number		Temperature limit

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