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 two versions (eyePlate-200 and eyePlate-300) with plate areas of 200mm^2 and 300mm^2 respectively. 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 and an external diameter of 0.63mm and an internal lumen of 0.30mm.

Model	Surface area	Tube length	Plate length	Plate width
eyePlate-200	200mm^2	28-30mm	16.8mm	14.5mm
eyePlate-300	300mm^2	28-30mm	18.9mm	18.5mm

INDICATIONS FOR USE:
The eyePlate is intended to manage intraocular pressure in glaucoma patients 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.

eyePlate-200 **eyePlate-300**

Figure 1: The eyePlate illustrated in its two available sizes: eyePlate-200 (left) and eyePlate-300 (right).

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/ADVERSE EVENTS:
The complications during and after surgery include, but are not limited to: IOP control troubles in the form of IOP spikes, flat or shallow chamber, hypotony, leaks at the level of the filtering bleb, inflammation and/or infection of the filtering bleb (blebitis), filtering bleb fibrosis and encystment; increased risk of developing cataract, choroidal hemorrhage, hyphema, serious choroidal effusion, phthisis bulbi, choroidal or retinal detachment, endophthalmitis, extrusion of the implant, exposure of the drainage tube, ocular movement limitation in lateral or upper/lower gaze, tube touch to cornea, macular or corneal edema, tube block by iris or vitreous, bullous keratopathy, iritis associated with anterior uveitis, diplopia and vision alteration.

DIRECTIONS FOR USE:
1. Examine the implant prior to implantation for proper size, model and expiration date. 2. Open the pouch 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 skill is required for the implantation of artificial drainage devices. Correct patient selection and meticulous surgery and postoperative care are required. The implanting 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. A fornix based conjunctival flap is used to dissect the conjunctiva and tenon's capsula from the sclera. The end plate is positioned between the rectus muscles and is attached to the sclera about 6-8 mm posterior to the limbus with 8-0 Prolene sutures through the fixation holes of the implant. The knots should be rotated into the fixation holes to prevent conjunctival erosion. 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. A 23-gauge needle 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. The tube should be ligated with a biodegradable ligature (7-0 or 8-0 Vicryl) or obstructed with a temporary plug (4-0 or 5-0 Prolene suture inserted in the lumen). 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. 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. Both models eyePlate-200 and eyePlate-300 are compatible with the eyeWatch implant.

HOW SUPPLIED/EXPIRATION DATE:
Each eyePlate-200 and eyePlate-300 implant is supplied sterile, within a double sterile pouch pack. The implants are sterilized using X-ray irradiation. Sterility is guaranteed unless the pouch 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.

RETURN OF DAMAGED/UNSTERILE PRODUCT:
Contact Rheon Medical SA for product return policy. Return the implant with proper identification and reason for return. Label return as biohazard.

PATIENT INFORMATION:
It is recommended that each patient receive information regarding glaucoma implants prior to the decision to implant.

IMPLANT CARD:
An ID 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 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 product or may be indicative of long-term problems associated with these types of products. Report any product related adverse event to: info@rheonmedical.com.

DISCLAIMER OF LIABILITY:
Rheon Medical SA accepts no liability for the choice of method or technique to implant the product or for the choice of the product for a particular patient or patient's condition.

SYMBOLS USED ON PACKAGING:

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

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