SYMBOLS USED ON PACKAGING

Symbol	English
	Consult instructions for use
STERILE R	Method of sterilisation using irradiation
	Do not reuse
	Do not resterilise
	Content is sterile unless inner package has been opened or damaged
SN	Serial number
	Use by [YYYY-MM] year-month
	Upper limit of temperature
	Manufacturer
EC REP	Authorised representative in the European community
	Date of manufacture
LOT	Batch code
REF	Catalog number

Advanced Ophthalmic Innovations Pte Ltd
101 Cecil Street, #25-04, Tong Eng Building, Singapore 069533

EC REP **MT Promedt Consulting GmbH**
Altenhofstrasse 80, 66386 St. Ingbert | Germany

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PRODUCT OF SINGAPORE

CE 0197

PAUL® GLAUCOMA IMPLANT

PLATE FOR PAUL® STABILITY SYSTEM

AOI
Advanced Ophthalmic Innovations

www.aoi.sg

Front Cover image is an artist impression of the product and is for illustrative purposes only. Actual products may vary.

EN

PAUL® GLAUCOMA IMPLANT DESCRIPTION

The PAUL® Glaucoma Implant is a glaucoma drainage device designed to treat glaucoma by regulating intraocular pressure in the patient's eye and preventing further progression of the disease. The device is constructed entirely from medical implantable grade silicone. This device has a length of 44.9mm, width of 23mm and an extraocular plate surface area of 342.1mm^2.

INDICATIONS FOR USE

For use in patients with medically uncontrollable glaucoma and poor surgical outcomes. This includes but is not limited to: neovascular glaucoma, aphakic/ pseudophakic glaucoma, patients who have failed conventional surgery, congenital glaucoma and secondary glaucoma due to uveitis, epithelial downgrowth, etc.

WARNINGS

The PAUL® Glaucoma Implant is intended for single use only. The implant must not be reused. Do not resterilise the implant by any method as the plate material may be damaged and the inner tube lumen may not be adequately made clear from potential infections or inflammatory substances. This will cause contamination and infection or other damage to patient's health, implant failure and lack of device sterility. Do not use the device if the integrity of the sterile packaging has been compromised. Do not use the implant outside of the expiration date.

DIRECTIONS FOR USE

1. Check the expiry date to ensure implant has not expired.
2. Examine the sterile pouch seal is intact before opening.
3. After opening remove the implant and examine the implant to ensure it is intact and not damaged.
4. Rinse the implant in sterile saline to remove any static charges.
5. Flush the tube with sterile saline to ensure tube flow. Do not use if there is no flow.

USAGE

Implanting surgeons should be skilled in the use of glaucoma drainage devices before using the PAUL® Glaucoma Implant and should also be familiar with the post-operative care required for management. The device is to be implanted sub-conjunctivally by a trained and experienced ophthalmic surgeon. Appropriate surgical techniques for implantation will have an effect on implant performance.

CONTRAINDICATIONS

Contraindications may include bacterial conjunctivitis, bacterial corneal ulcers, endophthalmitis, orbital cellulitis, bacteremia or septicemia, active scleritis and/or no light perception.

COMPLICATIONS / ADVERSE EFFECTS

Complications and adverse reactions during or following surgery may include corneal edema, corneal touch, iris/tube touch, synechia, exposed sclera graft, choroidal detachment, iritis, hyphema, tube obstruction, tube reaction, as well as known complications of the eye valve implant, including suprachoroidal hemorrhage, retinal detachment and shallow chamber.

HOW SUPPLIED / EXPIRATION DATE

The PAUL® Glaucoma Implant is supplied sterile in a double sealed pouch pack. The Instruction For Use, Implant Identification Card and Implant Barcode Stickers are also enclosed with the sterile package. It is recommended that each patient receives the Implant Identification Card attached with one of the Implant Barcode Stickers as a permanent record of the implant used by them. The implant is gamma sterilised. Sterility is assured unless pouch has been compromised, damaged, or if the expiration date has lapsed. Expiration date is indicated on outside of the box. The implant should not be used after the expiration date indicated.

DISCLAIMER OF LIABILITY

AOI makes no representation as to, and accepts no liability for, the choice of method or technique to implant or for the choice of the product for a particular medical condition. Please consult a qualified and licensed medical professional.

FURTHER INFORMATION

Further information on the product may be found at www.aoi.sg.

PAUL® GLAUCOMA IMPLANT
PLATE FOR PAUL® STABILITY SYSTEM