Advanced Ophthalmic Innovations

PAUL® GLAUCOMA IMPLANT

PLATE FOR PAUL® STABILITY SYSTEM

CE 0197 EN

PATIENT INFORMATION LEAFLET

PAUL® GLAUCOMA IMPLANT DESCRIPTION

The PAUL® Glaucoma Implant (P2015001) 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 and epithelial downgrowth.

WHAT IS GLAUCOMA

Glaucoma is defined as a group of diseases that damage the optic nerve, which is most commonly due to abnormally high intraocular pressure. In most types of glaucoma, the eye's drainage system becomes clogged and prevents the aqueous humor from being drained. As the fluid builds up, it causes an increase in the intraocular pressure. This abnormally high intraocular pressure causes damage to the optic nerve, which eventually causes blindness.

CAN GLAUCOMA BE CURED

Glaucoma is a chronic disease which means it cannot be cured, but it can be controlled to a large extent. Worsening of eyesight can be controlled by following a proper treatment regimen in the form of medicines / surgery with regular eye check-ups.

WHAT IS A GLAUCOMA DRAINAGE DEVICE

Conventional aqueous shunts, also known as glaucoma drainage devices, are permanently implanted into the eye. Most of the device (the end-plate) is positioned on the outside of the eye, just under the conjunctiva. A small tube is inserted into the front area of the eye, in front of the iris (the coloured part of the eye), where the fluid is able to drain through the tube into the end plate. The fluid collects here and can be re-absorbed into the body via the blood.

Aqueous shunts were initially considered as reserved options for high-risk patients or after trabeculectomy had failed. However, these have become increasingly popular and are now being used earlier because of their promising results.

BENEFIT OF THE SURGERY

Vision loss due to glaucoma is irreversible, but aqueous shunts aid in preserving vision and preventing further loss of sight. Aqueous shunts are permanently implanted into the eye, where they work to decrease intraocular pressure. They help to control pain and benefit is long term as they are classified as a long-term (continuous use for more than 30 days) invasive device.

ADVERSE EFFECTS

Glaucoma surgery carries risks just like any other surgery.

Haemorrhage (Bleeding)

Suprachoroidal haemorrhage which is bleeding inside the back of the eye and occasionally Hyphema which is bleeding inside the front of the eye occurs which settles within a few weeks.

Infection

An infection can affect entire eye or part of the eye. Infection inside the eye may occur, which can be very serious and may threaten vision. These infections can occur weeks, months, or even years after the surgery.

Blurred Vision

Permanent blurred vision is rare and generally settles with time.

Low pressure inside the eye (Hypotony)

Eye pressure can drop too low after the operation which is often corrected as the healing process occurs.

Irritation

Irritation, such as itching or tearing, can occur after implantation. This usually settles with drops after surgery and heals with time.

Cataract

There can be an increased risk of developing or worsening of age-related cataract after glaucoma drainage device implant surgery. However, cataracts are fairly easy to fix surgically.

Damage to the cornea

There is small risk that the tube portion of the implant rubs against the inner lining to the cornea. This can cause damage to the cells and result in cornea losing its clarity. There is a risk of fluid buildup in your cornea, causing swelling.

Tube Blockage

Fluid or eye tissue might get stuck in the tube, causing tube occlusion/blockage.

WARNINGS

The PAUL® Glaucoma Implant is intended for single use only. The implant must not be reused. Do not sterilize 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.

LIMITATIONS

Requires an intact conjunctiva and needs a full surgical wound opening.

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. When protected under specified conditions as per the label, the product has 2 years of shelf life following the date of manufacturing.

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.

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DIRECTIONS FOR USE

Implanting surgeons should be skilled in the use of glaucoma drainage device before using the PAUL® Glaucoma Implant and should also be familiar with the post-operative care management.

PREPARATION

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

WHAT TO EXPECT AFTER GLAUCOMA SURGERY

1. No operating a vehicle.
2. Rest, relax and avoid strenuous activity.
3. Follow doctor's orders for successful recovery
4. Take proper care and maintenance

WILL I NEED SURGERY AGAIN

For some people, the benefits of surgery last a long time. For others, the opening in the eye begins to close up and they need surgery again. You'll need regular check-ups with your doctor to test your eye pressure. That way, your doctor will be able to act fast if you need more treatment.

DISPOSAL INSTRUCTION

After explant, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable laws and regulation.

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.

In case of adverse event or serious complication that may be reasonably regarded as product related, please contact at quality@aoi.sg.

Reports may also be made directly to the Therapeutic Goods Administration via Medical Device Incident Reports (tga.gov.au). Or if you are based in New Zealand, Medsafe via the website https://www.medsafe.govt.nz/regulatory/DevicesNew/9AdverseEvent.asp. For European Union and other countries, reports may be made directly to national health/competent authority of the respective country.

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-DD] year-month-day
	Upper limit of temperature
	Manufacturer
EC REP	Authorised representative in the European community
	Date of manufacture
LOT	Batch code
REF	Catalog number

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EC REP

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