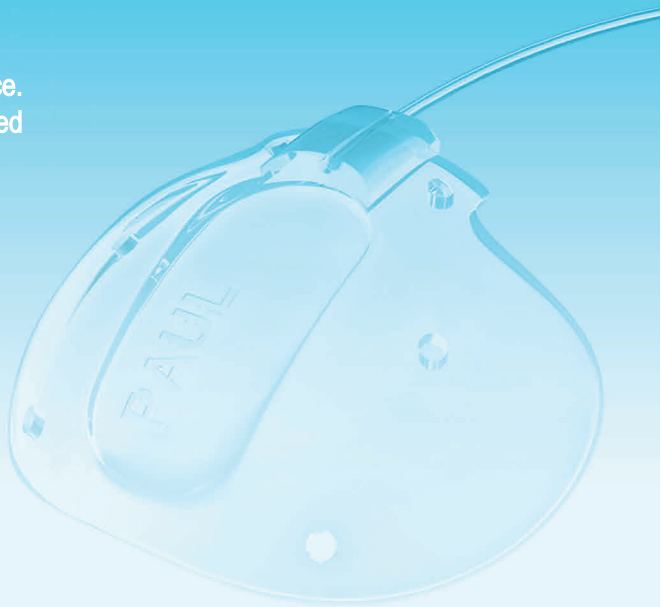
AOI
Advanced Ophthalmic Innovations

www.fciworldwide.com

www.aoi.sg

PAUL® GLAUCOMA IMPLANT

The PAUL® Glaucoma Implant is a novel glaucoma drainage device. PAUL has introduced many innovative design features and unified these into one device that delivers both Efficacy and Safety*.



*Vallabh, N.A., Mason, F., Yu, J.T.S. et al. "Surgical technique, perioperative management and early outcome data of the PAUL® glaucoma drainage device". Eye (2021).
*Triolo G., Koh V. and al. "Paul® Glaucoma Implant in the Surgical Management of refractory Glaucoma : 12 months Safety and Efficacy Outcomes of a novel Aqueous Shunt Implant". Poster American Glaucoma Society (2020)

KEY NOVEL FEATURES OF PAUL® GLAUCOMA IMPLANT

Micro-sized Tube

- **Small Internal Caliber**
  Balances flow resistance, safeguards against early hypotony*
- **Small External Caliber**
  Decreases risk of corneal touch, minimizes tube erosion*

Optimized Endplate Design

- **Optimal Large Plate Surface Area**
  More area available for aqueous drainage
- **Ideal Drainage Shape**
  Less device area covered by recti muscles

Advanced Device Composition

- **Implantable Medical-grade Silicone**
  New level of device pliability, facilitates implantation
- **Flexible Device**
  Decreases micro-abrasion, reduces wound scarring

*"PAUL® Glaucoma Implant" brochure, 2022, Advanced Ophthalmic Innovations Pte Ltd

PAUL® REDUCES IOP EFFECTIVELY AND SAFELY

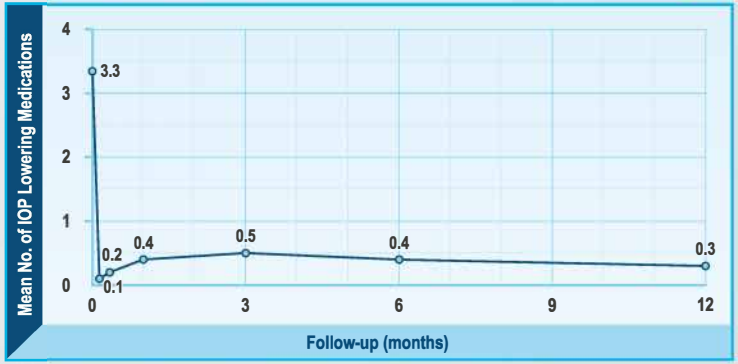
Results from a multi-center clinical study of PAUL Glaucoma Implant showed significant reduction of IOP and decreased need for IOP-lowering medications.[1]

A 62% reduction in IOP was observed 12 months after surgery when compared with the highest mean preoperative IOP of 34.3 mmHg. The postoperative IOP was 14.9 mmHg, 14.5 mmHg, 13.8 mmHg, and 13.2 mmHg at 1, 3, 6, and 12 months respectively. Similarly, there was a significant reduction in glaucoma medications needed to maintain the lowered IOP, from 3.3 before surgery to 0.3 12 months after surgery.

At the end of 1 year, 93% of patients were classified as qualified success, 69% were classified as complete success, and 5% were classified as failure. Definitions of these measures are consistent with World Glaucoma Association Guidelines.[2] The tables below summarize the postoperative outcomes of the participants in the study.

IOP Reduction Post-Operation

Glaucoma Medication Reduction Post-Operation



1 Koh V, Chew P, Triolo G, et al. Treatment outcomes using the PAUL glaucoma implant to control intraocular pressure in eyes with refractory glaucoma. Ophthalmol Glaucoma. 2020;3:350-9.

2 Heuer DK, Barton K, Grehn F, et al. Consensus on definitions of success. In: Shaarawy TM, Sherwood MB, Grehn F, editors. Guidelines on Design and Reporting of Surgical Trials. World Glaucoma Association; 2008. p. 15-24. Specifically, complete success was defined as unmedicated IOP of 21 mmHg or less and more than 5 mmHg and reduced by 20% or more from baseline at the 6-and 12-month visits. Qualified success was defined similarly and included eyes receiving medical treatment to lower the IOP. Failure was defined as IOP of more than 21 mmHg or less than 20% reduction from the preoperative baseline on 2 consecutive visits, 3 months or more after surgery; persistent late hypotony, defined as IOP less than 6 mmHg on 2 consecutive visits after 3 months; additional glaucoma surgery; loss of light perception vision; or removal of the implant for any reason.

DESIGN ADVANCEMENTS
PERFORMANCE ADVANTAGES

THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC.
ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE.

Contact us: info@aoi.sg

The PAUL® Glaucoma Implant, is a Class IIb medical device distributed by FCI S.A.S. and manufactured by Advanced Ophthalmic Innovations Pte Ltd. Notified Body: TÜV Rheinland LGA Products GmbH CE n°0197. The product listed in this publication may not be registered in your country. Contact your local distributor to find out what is available to you. This publication is not intended for distribution in the USA.

AOI
Advanced Ophthalmic Innovations

Advanced Ophthalmic Innovations Pte Ltd

101 Cecil Street, #25-04
Tong Eng Building, Singapore 069533

Contact us at info@aoi.sg

WWW.AOI.SG

FCI®
a ZEISS company

Distributed by FCI S.A.S.

CONTACT INFORMATION

Austria & Germany
M. Stefan Wickerath
Tel.: +49 2235 7948 880
Email: stefan.wickerath@fci.fr

Belgium
M. Dennis Jonniaux
Tel.: +32 (0) 479 45 83 00
Email: dennis.jonniaux@fci.fr

FCI25.002 Ind.A - Janvier 2025 - Société par Actions Simplifiées au capital de 46 909€ - SIREN 351 670 385