NEW WORLD MEDICAL

Humanity's Vision Is Our Focus

The Ahmed® Glaucoma Valve

MEDINOVA

Dr. A. Mateen Ahmed

President & CEO - New World Medical

New World Medical is a high tech medical device company whose goal is to help humanity lead a better life through improved technology and innovation. Presently New World Medical focus is in different areas of Ophthalmology.

The Ahmed Glaucoma Valve has been successfully demonstrated to work in all types of glaucoma cases, particularly Neovascular, Congenital, and Uveitic glaucoma. New World Medical manufactures and markets its own products. In the U.S., New World Medical markets its products through a team of sales representatives. In the international market, the company has exclusive distribution network around the globe selling all over the world. Along with its own products, New World Medical also distribute human tissue such as sclera and pericardium.

The R&D division of New World Medical is actively involved in developing new products through collaborations with number of renowned medical universities and ophthalmologists around the world. These partnerships allow New World Medical to develop products through a first-hand involvement in the medical device industry.

Dr. A. Mateen Ahmed founded New World Medical, and serves as President/CEO and Chairman of the Board of Directors. The vision of Dr. Ahmed and New World Medical is to help the lives of people around the world. This has earned the company many accolades, including the “Have a Heart, International Goodwill, and Understanding Award” given by Soroptimist International.

Mechanics of the Ahmed Glaucoma Valve

The Venturi Effect:

To reduce internal friction within the valve system, the Ahmed Glaucoma Valve utilizes a specially designed, tapered trapezoidal chamber to create a Venturi effect to help aqueous flow through the device. The inlet velocity of aqueous entering the larger port of the venturi chamber increases significantly as it exits the smaller outlet port of the tapered chamber. In an Ahmed Glaucoma Valve, this increased exit velocity greatly helps in evacuating aqueous from the valve, thereby helping to reduce valve friction.

Non-Obstructive, Self-Regulating Valve Mechanism:

The Ahmed Glaucoma Valve has no obstruction in its path of fluid flow. For the flow to be non-obstructive, a particle large enough to pass through the lumen of the tube, will easily pass through the much larger opening of the Venturi-Flow™ chamber. The elastic membranes help to regulate fluid flow at all times, consistently by changing their shape. The tension on these membranes is responsible of reducing hypotony.

$$\frac{P_1}{W} + \frac{V_1^2}{2g} + Z_1 = \frac{P_2}{W} + \frac{V_2^2}{2g} + Z_2$$

SINCE $Z_1 = Z_2$,

$$\frac{P_1}{W} + \frac{V_1^2}{2g} = \frac{P_2}{W} + \frac{V_2^2}{2g}$$

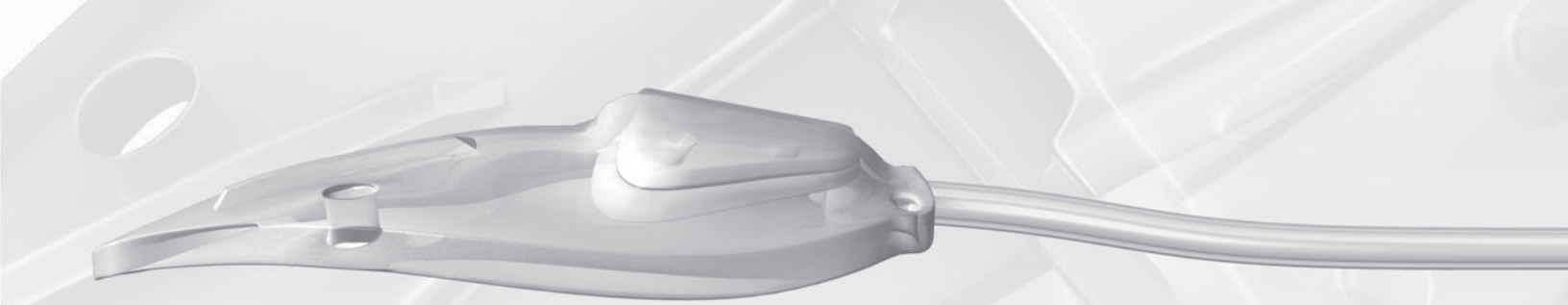
$$\frac{P_1 - P_2}{W} = \frac{V_2^2 - V_1^2}{2g}$$

$$P_1 - P_2 = \frac{W}{2g}\left[V_2^2 - V_1^2\right] \text{ -or-}$$

$$P_1 - P_2 \propto V_2^2 - V_1^2$$

Model FP7

Ahmed Glaucoma Valve
Flexible Plate



Features:

+ Made of medical grade silicone
+ Immediate reduction of intraocular pressure
+ Unique, non-obstructive valve system to prevent excessive drainage and chamber collapse
+ Implanted in a single-stage procedure
+ Tapered profile for easy insertion
+ Silicone plate
+ Aqueous percolation holes
+ Thinner Plate

Plate/Valve Specifications:

Thickness: 2.1mm

Width: 13.0mm

Length: 16.0mm

Surface Area: 184.0mm^2

Tube Specifications:

Length: 25.4mm

Inner Diameter: 0.305mm

Outer Diameter: 0.635mm

Materials:

Valved Plate Body: medical-grade silicone

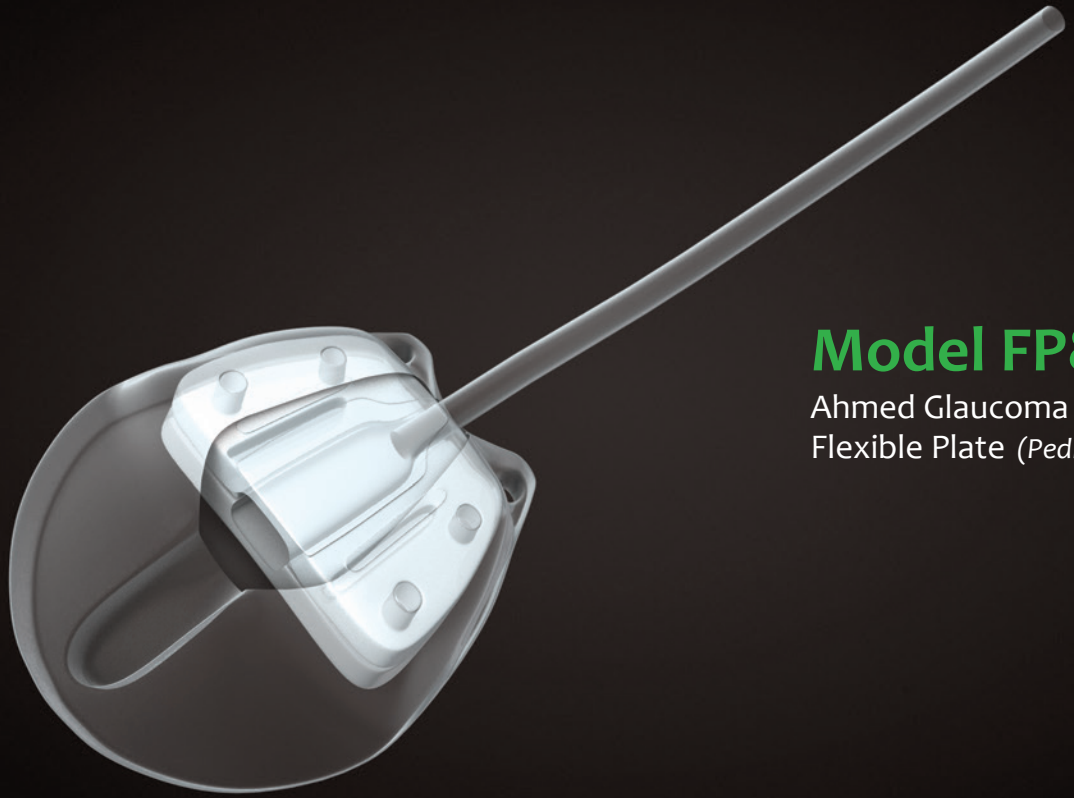
Drainage Tube: medical-grade silicone

Valve: medical-grade silicone, elastomer membrane

Valve Casing: medical-grade polypropylene

Ordering Information:

Model: FP7
(Ahmed Flexible Plate)



Model FP8

Ahmed Glaucoma Valve
Flexible Plate *(Pediatric)*

Features:

+ Made of medical grade silicone
+ Used for pediatrics or small globes
+ Immediate reduction of intraocular pressure
+ Unique, non-obstructive valve system to prevent excessive drainage and chamber collapse
+ Implanted in a single-stage procedure
+ Eliminates drainage tube ligature sutures, "rip-chord" sutures, and occluding sutures
+ Thinner Plate

Plate/Valve Specifications:

Width: 11.0mm

Length: 11.0mm

Surface Area: 102.0mm^2

Thickness: 2.1mm

Tube Specifications:

Length: 25.4mm

Inner Diameter: 0.305mm

Outer Diameter: 0.635mm

Materials:

Valved Plate Body: medical-grade silicone

Drainage Tube: medical-grade silicone

Valve: medical-grade silicone, elastomer membrane

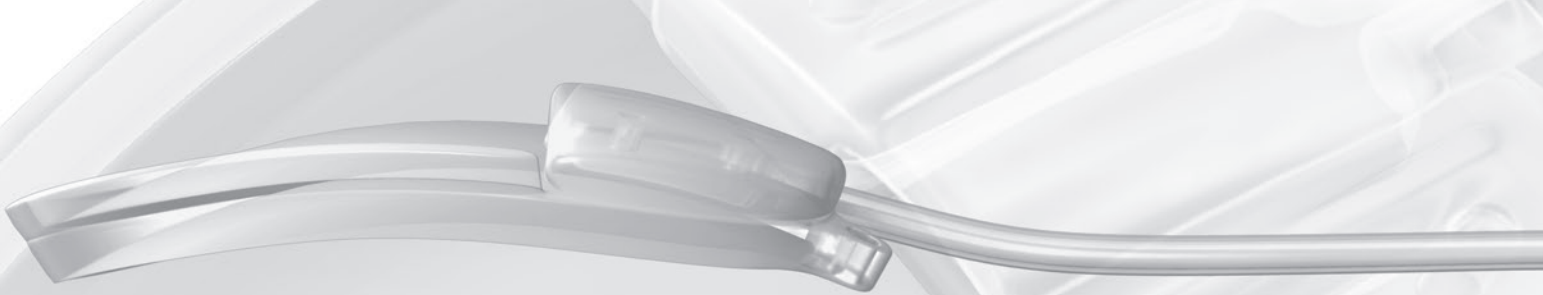
Valve Casing: medical-grade polypropylene

Ordering Information:

Model: FP8
(Ahmed Flexible Plate - *Pediatric*)

Model S2

Ahmed Glaucoma Valve



Features:

+ Immediate reduction of intraocular pressure
+ Unique, non-obstructive valve system to prevent excessive drainage and chamber collapse
+ Implanted in a single-stage procedure
+ Eliminates drainage tube ligature sutures, "rip-chord" sutures, and occluding sutures

Plate/Valve Specifications:

Thickness: 1.6mm

Width: 13.0mm

Length: 16.0mm

Surface Area: 184.0mm^2

Tube Specifications:

Length: 25.4mm

Inner Diameter: 0.305mm

Outer Diameter: 0.635mm

Materials:

Valved Plate Body: medical-grade polypropylene

Drainage Tube: medical-grade silicone

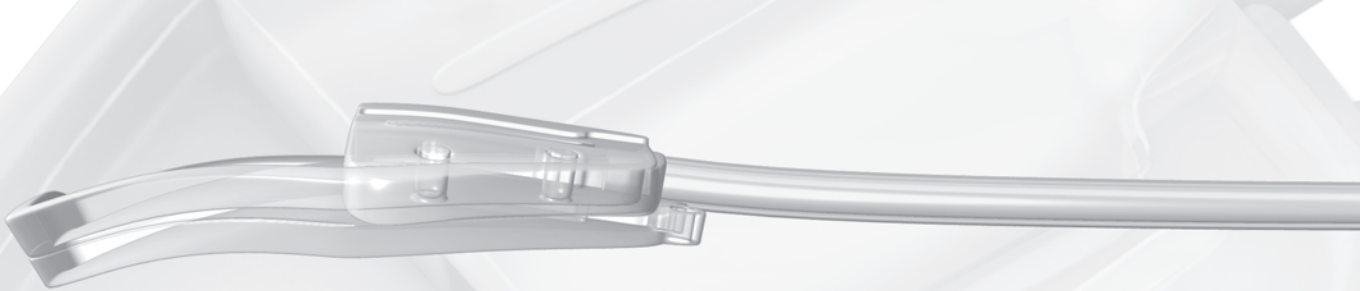
Valve: medical-grade silicone, elastomer membrane

Ordering Information:

Model: S2
(Ahmed Glaucoma Valve)

Model S3

Ahmed Glaucoma Valve
(Pediatric)



Features:

+ Used for pediatrics or small globes
+ Immediate reduction of intraocular pressure
+ Unique, non-obstructive valve system to prevent excessive drainage and chamber collapse
+ Implanted in a single-stage procedure
+ Eliminates drainage tube ligature sutures, “rip-chord” sutures, and occluding sutures

Plate/Valve Specifications:

Width: 9.3mm

Length: 10.0mm

Surface Area: 85.0mm^2

Tube Specifications:

Length: 25.4mm

Inner Diameter: 0.305mm

Outer Diameter: 0.635mm

Materials:

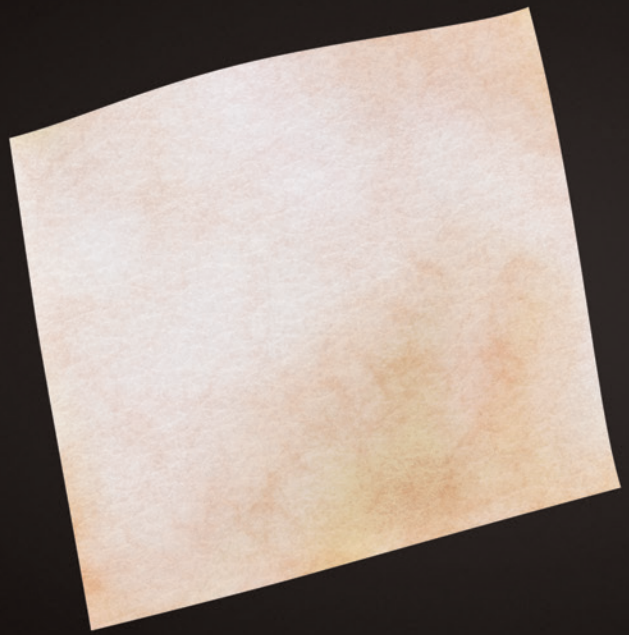
Valved Plate Body: medical-grade polypropylene

Drainage Tube: medical-grade silicone

Valve: medical-grade silicone, elastomer membrane

Ordering Information:

Model: S3
(Ahmed Glaucoma Valve - Pediatric)



Human Allograft Tissue

Pericardium and Sclera

Features:

+ Biocompatible human tissue for leaking blebs
+ Gamma sterilized
+ 2.5 years shelf life
+ Nominal thickness 0.5mm
+ Available Freeze-Dried or Hydrated
+ Available full thickness sclera or pericardium
+ Can be used as ocular tissue for other cosmetic uses

Ordering Information:

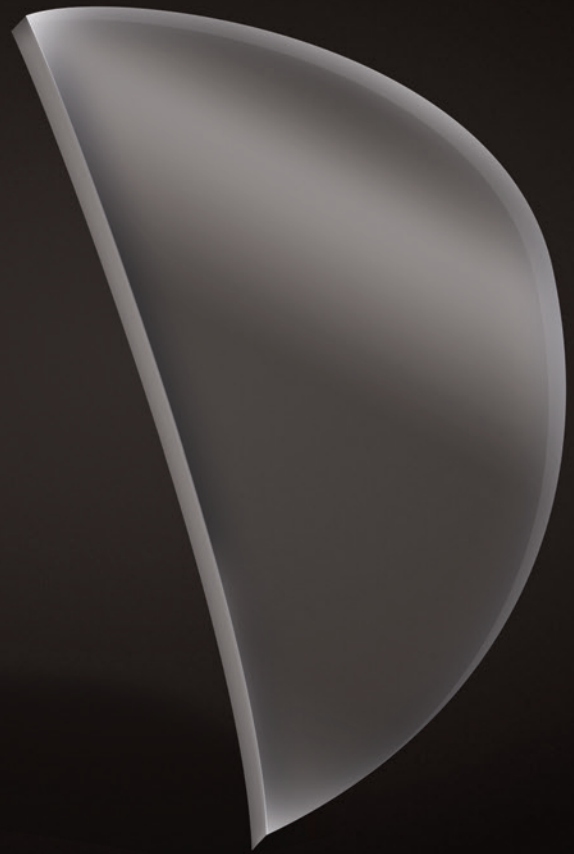
TSH: (Human Sclera)

TPH: (Hydrated Pericardium)

TPD: (Freeze-Dried Pericardium)

Corneal Tissue

Long Term Preserved Cornea



Features:

+ Clear Graft for better cosmetic result
+ Assumes the color of underlying structure (cornea or sclera)
+ Thinner than other graft materials
+ Allows better patient comfort
+ Ready to use: Just rinse in saline or antibiotic solution and proceed
+ Biomechanically comparable to fresh corneal material
+ One year shelf life at room temperature storage

Indications:

Glaucoma Valve Tube Overlay

Glaucoma Bleb Patch

Patch Allograft

Corneal Tissue Specifications:

5 x 10mm

200 to 300 microns

Ordering Information:

TCC: Corneal Tissue

Model TE

Tube Extender™

Tube Extender Features:

+ Provides extra tube length
+ Provides leak-proof junction between tubes
+ Helpful when drainage tube is cut too short
+ Can be used with other drainage devices
+ Easily sutured onto sclera

Ordering Information:

Model: TE (Tube Extender)

Model TI

Tube Inserter™

Features:

+ Notched tip secures valve tube
+ Provides rigidity to valve tube for easy insertion into the anterior chamber
+ Stainless steel
+ Serrated grip
+ Shorter tip helps to provide better view through microscope
+ Reusable and inexpensive
+ Can be used with any drainage device

Ordering Information:

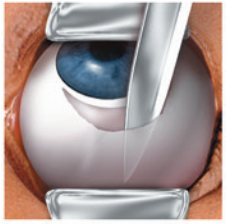
Model: TI (Tube Inserter)

Surgical Procedure

1.

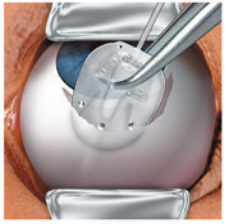
The implant should be examined and primed prior to implantation. Priming is accomplished by injecting 1cc balanced salt solution or sterile water through the drainage tube and valve, using a blunt **26 gauge cannula**.

2.



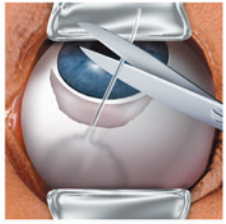
A fornix-based incision is made through the conjunctiva and Tenon's capsule. A pocket is formed at the superior quadrant between the medial or lateral rectus muscles by blunt dissection of Tenon's capsule from the episclera.

3.



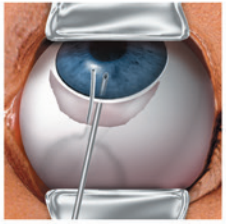
The valve body is inserted into the pocket between the rectus muscles and sutured to the episclera. The leading edge of the plate should be at least **8-10mm from the limbus**.

4.



The drainage tube is trimmed to permit a **2-3 mm** insertion of the tube into the anterior chamber (AC). The tube should be bevel cut to an anterior angle of 30° to facilitate insertion.

5.

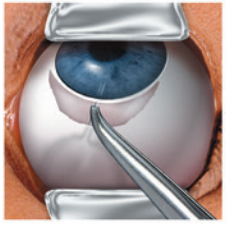


A paracentesis is performed, and the AC is entered at 1-2 mm away from the limbus with a sharp 23 gauge needle to create a needle track, parallel to the iris.

Caution: Care must be taken to ensure that the drainage tube does not contact the iris or corneal endothelium after insertion.

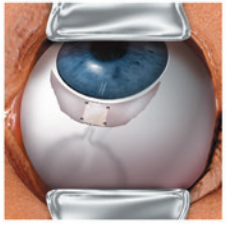
Note: Some surgeons prefer to enter the AC from at least 3mm away from the limbus.

6.

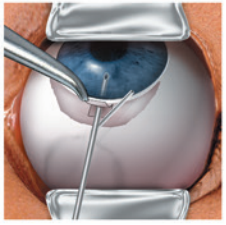


The drainage tube is inserted approximately **2-3 mm** into the AC through the needle track created in step 5.

7.



The exposed drainage tube is covered with a piece of preserved, donor sclera, pericardium, cornea, or other suitable patch graft material which is sutured into place and the conjunctiva is closed.



NOTE: As an alternative to Step 7, a 2/3 thickness limbal-based scleral flap may be made. The tube is inserted into the AC through a 23 gauge needle puncture made under the flap. The flap is sutured closed.

The steps illustrated here are intended as a **guideline only**, and do not represent recommended treatment for any particular patient. The use of any specific surgical technique or maneuver is at the sole discretion of the surgeon. Surgeons should be familiar with the use of glaucoma drainage devices and post-operative care considerations before implanting any drainage device. Reference papers and surgical video tapes are available upon request.

Patents No. 5, 071, 408
Patents No. 5, 411, 473
Patents No. 5, 785, 674
Patents No. 6, 261, 256
Patents No. 5, 681, 275
Patents No. 5, 616, 118

Caution: (U.S.) Federal Law restricts these devices to sale by or on the order of a physician.

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> oftalmologia

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ABC Study highlights improved safety with the Ahmed Glaucoma Valve

The ABC study is the largest and longest prospective clinical trial comparing two aqueous shunts, with an enrollment of 276 subjects followed over 5 years.

"Conclusions: Similar rates of surgical success were observed with the both implants at 5 years. The Baerveldt Group Implant produced greater IOP reduction and a lower rate of glaucoma reoperation than the Ahmed Glaucoma Valve, but the **Baerveldt Glaucoma Implant was associated with twice as many failures because of safety issues."** [1]

Serious Complication Associated with Reoperation and/or Vision Loss in the ABC Study

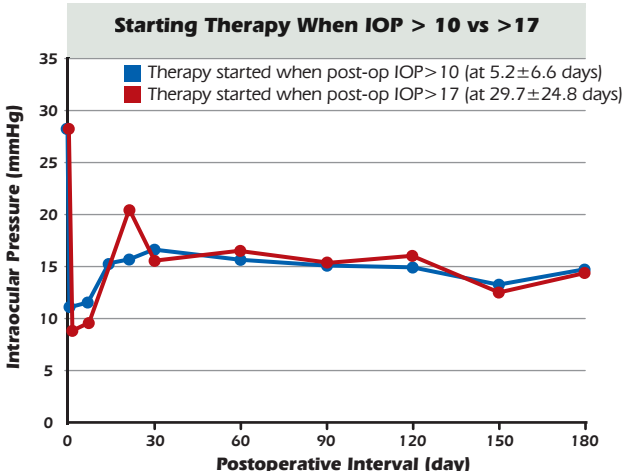
	Ahmed Group (n = 143)	Baerveldt Group (n = 133)
Reoperation for complications	16 (14.3%)	24 (19.5%)
Vision loss of ≥ 2 Snellen lines		
Persistent corneal edema	1	1
Persistent corneal edema + hypotony maculopathy	0	1
Persistent corneal edema + tube-corneal touch	0	2
Cystoid macular edema	0	1
Total number of subjects with serious complications	17 (15.9%)	29 (24.7%)

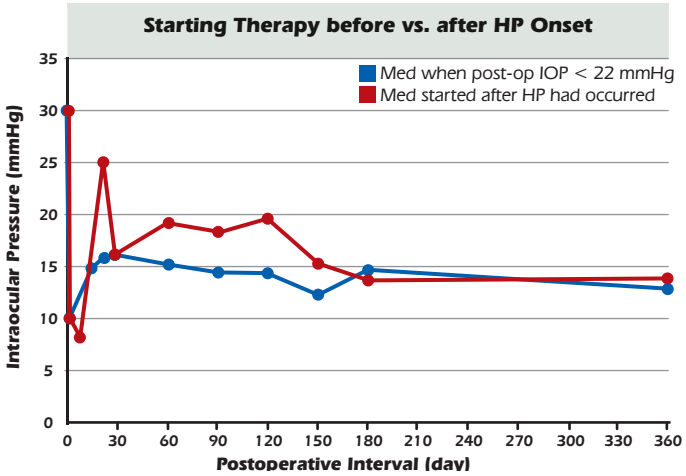
"In addition, there were more cases of phthisis bulbi in the Baerveldt Glaucoma Implant BG 101-350 group than the Ahmed Glaucoma Valve FP7 group, perhaps due to the fact the Baerveldt Glaucoma Implant BG 101-350 group has a similar proportion of subjects experiencing failures due to persistent hypotony. It may be that the larger end plate of the Baerveldt Glaucoma Implant BG 101-350, which is generally considered to provide lower long-term IOPs, appears to put patients at increased risk of persistent hypotony and phthisis bulbi as well." [2]

Aqueous Suppressant Therapy [3]

"Hypertensive Phase: After tube implantation, an initial reduction of IOP is frequently followed by a rebound IOP increase called the hypertensive phase (HP)." This typically occurs from 1 week to 3 months after surgery.

"In summary, we demonstrated that early initiation of aqueous suppressant treatment after Ahmed Glaucoma Valve implantation improves the success rate of the procedure, provides better IOP control, and reduces the likelihood of a hypertensive phase." One main benefit of this technique is the reduction in the IOP spike associated with the HP.



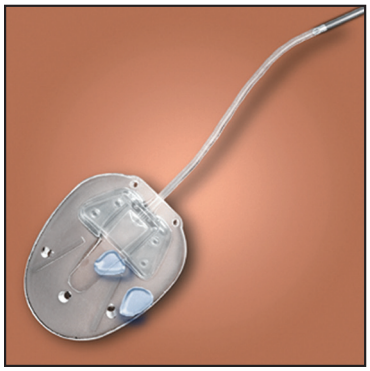


It is best to start aqueous suppressant therapy as soon as IOP rises above 10mmHg post-op.
This does not increase complication rate.

[1] **Budenz, Donald L, et al.** *"Five-Year Treatment Outcomes in the Ahmed Baerveldt Comparison Study." Ophthalmology (2014): 1-9.*
[2] **Budenz, Donald L, et al.** *"Postoperative Complications in the Ahmed Baerveldt Comparison Study during 5-Years of Follow-up." AJO (2015).*
[3] **Law, Simon K, et al.** *"Early Aqueous Suppressant Therapy on Hypertensive Phase Following Glaucoma Drainage Device Procedure." Journal of Glaucoma (2014).*

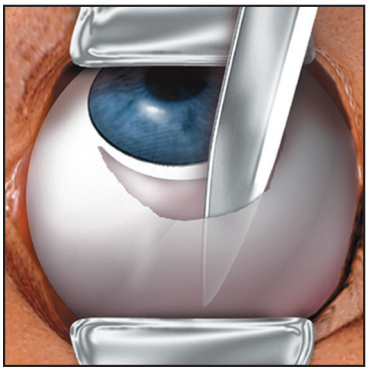
The Ahmed® Glaucoma Valve Surgical Procedure

Step 1



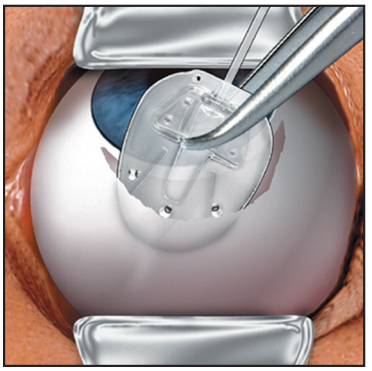
The implant should be examined and primed prior to implantation. Priming is accomplished by injecting 1cc balanced salt solution or sterile water through the drainage tube and valve, using a blunt **26 gauge cannula**.

Step 2



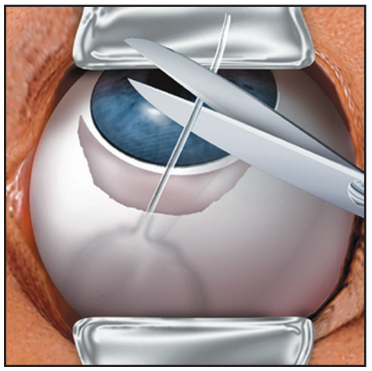
A fornix-based incision is made through the conjunctiva and Tenon's capsule. A pocket is formed at the superior quadrant between the medial or lateral rectus muscles by blunt dissection of Tenon's capsule from the episclera.

Step 3



The valve body is inserted into the pocket between the rectus muscles and sutured to the episclera. The leading edge of the plate should be at least **8-10mm from the limbus**.

Step 4



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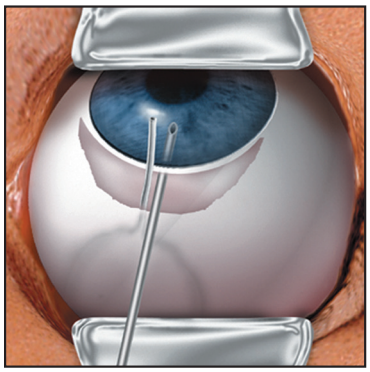
Step 5



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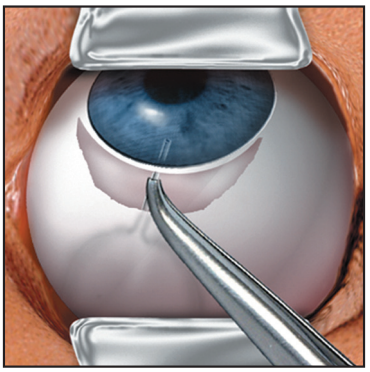
Note: Some surgeons prefer to enter the AC from at least 3mm away from the limbus.

Step 6



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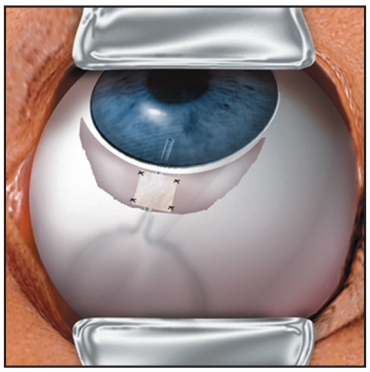
Step 7



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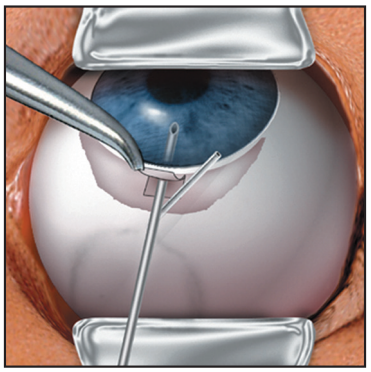

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