# The Ahmed® Glaucoma Valve

## Model FP7

Manufactured by

NEW WORLD
MEDICAL

USA

CE
0459

℞only **Caution:** Federal (USA) law restricts this device to sale or on the order of a physician.

English (en)

# The Ahmed® Glaucoma Valve
## Model FP7
Product Information

## DESCRIPTION
The Ahmed® Glaucoma Valve Model FP7 (AGV-FP7) is a valved aqueous drainage implant designed to regulate intraocular pressure in eyes suffering from refractory glaucoma. The Ahmed® device consists of a valve mechanism and a plate. The valve mechanism is comprised of a silicone drainage tube and polypropylene body which houses a silicone elastomer valve membrane. The polypropylene body protects the valve membrane from blockage by fibrous tissue. The plate conforms to the shape of the globe at its equator and provides a surface where fluid can be dispersed. The plate material of the Model FP7 is silicone. The device is for single use only.

## INDICATIONS
The Ahmed® Glaucoma Valve Model FP7 is indicated for the management of refractory glaucomas, where previous surgical treatment has failed, or by experience is known not to provide satisfactory results. Such refractory glaucomas can include neovascular glaucoma, primary open angle glaucoma unresponsive to medication, congenital or infantile glaucoma, and refractory glaucomas resulting from aphakia or uveitis.

## CONTRAINDICATIONS
a. Bacterial conjunctivitis
b. Bacterial corneal ulcers
c. Endophthalmitis
d. Orbital Cellulitis
e. Bacteremia or septicemia
f. Active scleritis
g. No light perception

## COMPLICATIONS AND ADVERSE REACTIONS
Corneal Edema
Corneal Touch
Iris/Tube Touch
Synechia
Exposed Sclera Graft
Choroidal detachment
Iritis
Hyphema
Tube Obstruction
Tube Retraction

as well as known complications of aqueous shunts and general intraocular surgery including hypotony, shallow chamber, hyphema, choroidal effusion, suprachoroidal hemorrhage, choroidal detachment, retinal detachment, iritis, synechia, cataract, conjunctival buttonhole, phthisis bulbi, bullous keratopathy, uveitis and endophthalmitis.

## WARNINGS, PRECAUTIONS
Do not use the device if sterile package integrity has been compromised. Do not re-sterilize the implant. Before using the Ahmed® Glaucoma Valve, the implanting surgeon should be skilled in glaucoma filtering procedures and familiar with the use of drainage devices, as well as post-operative care required.

Priming the valve is essential for proper functioning of the valve. Do not implant the valve without priming it.

Ensure that the valve is primed before operating on the patient. Inherently, the force required to prime the valve may vary between units. Some valves may require more force applied over a longer period of time than other valves in order to perform the priming operation. If you are unable to prime the valve, do not use the device. The manufacturer will exchange the device.

In rare cases, you may be unable to prime the valve due to crimped or pinched tubing. In such a situation, do not use the device. The manufacturer will exchange the device.

Using a needle for priming can puncture the tube resulting in an undesirable leak or inability to prime. Only use a blunt cannula to prime the valve.

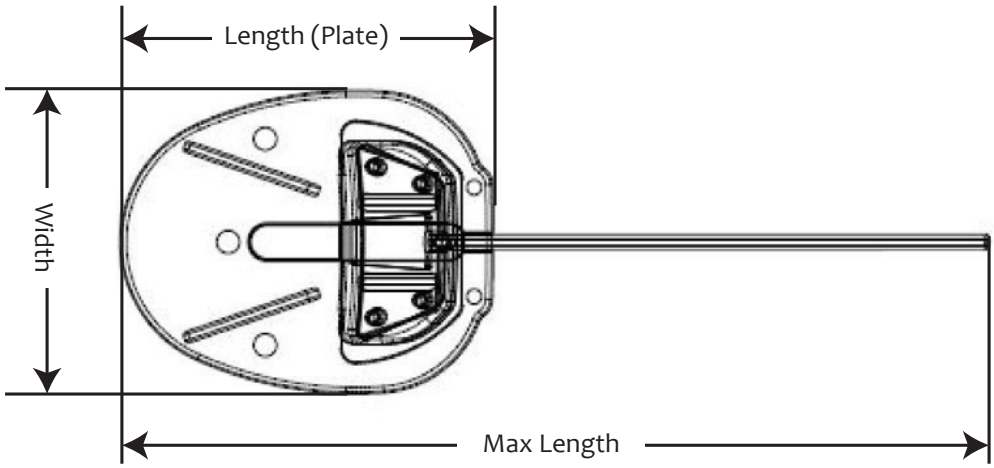
The Ahmed® Glaucoma Valve is intended for single use, it shall not be reused. It shall be discarded to avoid deterioration, cross contamination and/or infection.

Tampering with the valve can cause malfunctioning of the valve.

**AGV-FP7**

**Trade Name: Ahmed® Glaucoma Valve Model FP7**

# Top View




# Side View


**End Plate:** Medical Grade Silicone
**Drainage Tube:** Medical Grade Silicone
**Valve Membrane:** Medical Grade Silicone
**Valve Casing:** Medical Grade Polypropylene (PP)
**Adhesive:** Medical Grade Silicone Glue

**Maximum thickness:** 2.1 mm
**Max Length:** 41.4 mm
**Plate Length:** 16.0 mm
**Device Overall Width:** 13.0 mm
**Drainage Area/Explant Surface Area:** 184 $mm^2$

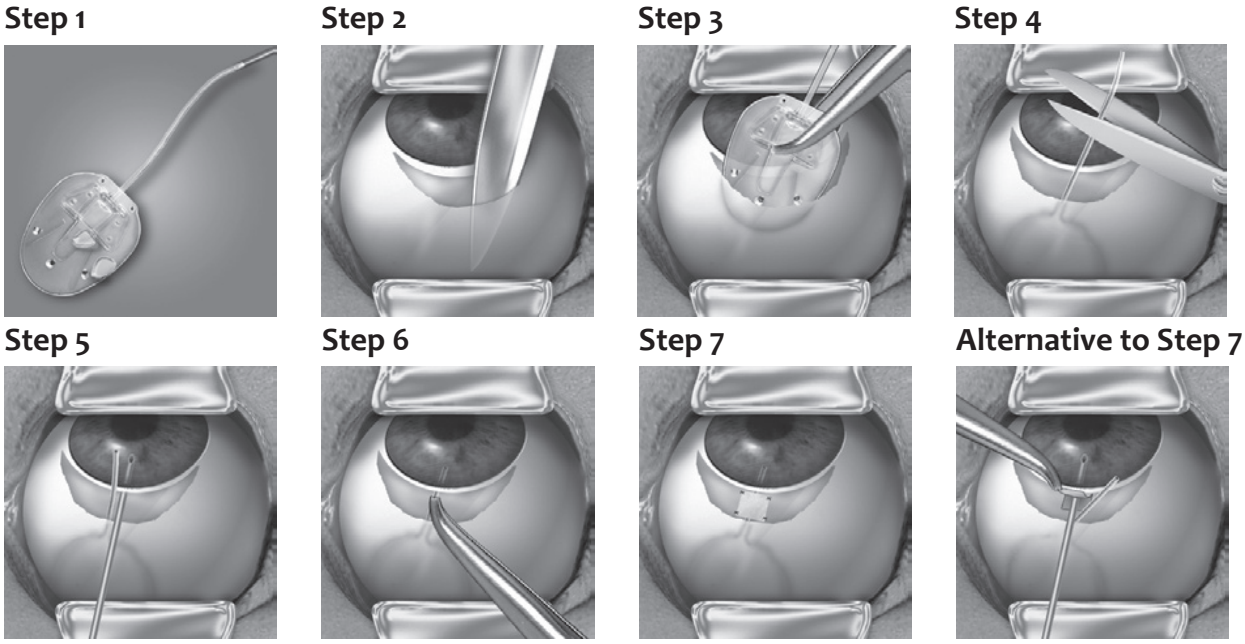
## HOW SUPPLIED

The implant is supplied sterile in a sealed pouch. Product Information, Patient Chart Labels, Implant Notification Card, and a Patient ID Card are also enclosed with the sterile package. The implant has been terminally sterilized by Gamma Radiation. Sterility is assured provided that the peel pouch has not been opened or damaged, and the sterility expiration date has not lapsed. The peel pouch is intended to be opened using sterile technique, allowing the implant to be dropped into the sterile field.

**NOTE: The manufacturer disclaims all warranties expressed or implied, including but not limited to suitability for a particular purpose.**

## SURGICAL PROCEDURE

# Figure 1




Refer to figure 1 for the illustration of each step. The steps described 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.

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 way 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. The leading edge of the plate should be 8-10 mm from the limbus.
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.

## CLINICAL STUDY RESULTS

Clinical data for the AGV-FP7 can be found in the citations referenced below. This includes safety and effectiveness data and information on adverse effects and complications associated with the AGV-FP7.

1. The Ahmed Baerveldt Comparison Study. This study compared the long-term outcomes and complication of the Ahmed Glaucoma Valve model FP7 (AGV-FP7) and the Baerveldt glaucoma implant. This was a multicenter, prospective, randomized, controlled clinical trial with several relevant publications which have been cited here.

   Barton K, Gedde SJ, Budenz DL, Feuer WJ, Schiffman J. The Ahmed Baerveldt Comparison Study methodology, baseline patient characteristics, and intraoperative complications. Ophthalmology. 2011 Mar;118(3):435-42. PubMed PMID: 20932581; NIHMSID: NIHMS233027; PubMed Central PMCID: PMC3020244.

   Budenz DL, Barton K, Feuer WJ, Schiffman J, Costa VP, et al. Treatment outcomes in the Ahmed Baerveldt Comparison Study after 1 year of follow-up. Ophthalmology. 2011 Mar;118(3):443-52. PubMed PMID: 20932583; NIHMSID: NIHMS233028; PubMed Central PMCID: PMC3020266.

   Budenz DL, Barton K, Gedde SJ, Feuer WJ, Schiffman J, et al. Five-year treatment outcomes in the Ahmed Baerveldt comparison study. Ophthalmology. 2015 Feb;122(2):308-16. PubMed PMID: 25439606; NIHMSID: NIHMS625185; PubMed Central PMCID: PMC4306613.

   Budenz DL, Feuer WJ, Barton K, Schiffman J, Costa VP, et al. Postoperative Complications in the Ahmed Baerveldt Comparison Study During Five Years of Follow-up. Am J Ophthalmol. 2016 Mar;163:75-82. e3. PubMed PMID: 26596400; NIHMSID: NIHMS746915; PubMed Central PMCID: PMC4901387.

2. Comparison of Polypropylene and Silicone Ahmed Glaucoma Valves. This study was conducted to evaluate and compare clinical outcomes after implantation of the silicone plate Ahmed Glaucoma Valve Model FP7 (AGV-FP7) and the polypropylene plate Ahmed Glaucoma Valve Model S2 (AGV-S2). This was a prospective, multicenter, comparative study.

   Ishida K, Netland PA, Costa VP, Shiroma L, Khan B, et al. Comparison of polypropylene and silicone Ahmed Glaucoma Valves. Ophthalmology. 2006 Aug;113(8):1320-6. PubMed PMID: 16877071.

3. Comparison of silicone and polypropylene Ahmed glaucoma valves: two-year follow-up. The purpose of this study was to compare the safety and efficacy of the silicone Ahmed glaucoma drainage device (AGV-FP7) and the polypropylene Ahmed glaucoma drainage device (AGV-S2). This study was a single surgeon, retrospective, consecutive case series.

   Mackenzie PJ, Schertzer RM, Isbister CM. Comparison of silicone and polypropylene Ahmed glaucoma valves: two-year follow-up. Can J Ophthalmol. 2007 Apr;42(2):227-32. PubMed PMID: 17392844.

## SYMBOLS USED ON PACKAGING

| Symbol | English |
|---|---|
|  | Manufacturer |
|  | Authorised representative in the European Community |
|  | Do not re-use |
|  | Date of Manufacture YYYY-MM |

| Symbol | English |
|---|---|
|  | Consult Instructions for Use |
|  | Use-by date |
|  | Sterilized using irradiation |
|  | Batch Code |

| Symbol | English |
|---|---|
|  | Do not resterilize |
|  | Serial Number |
|  | Do not use if package is damaged |

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