The Ahmed® Glaucoma Valve

Model FP8

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 FP8
Product Information

DESCRIPTION
The Ahmed® Glaucoma Valve Model FP8 (AGV-FP8) 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 an end plate. The valve mechanism is comprised of a silicone drainage tube and polypropylene casing which houses a silicone elastomer valve membrane. The polypropylene casing protects the valve membrane from blockage by fibrous tissue. The end plate, made from silicone, conforms to the shape of the globe at its equator and provides a surface from which fluid can be dispersed. Due to a smaller end plate surface area compared to other glaucoma drainage devices such as the AGV-FP7, the AGV-FP8 can be used in situations where a smaller end plate device is desired.

INDICATIONS
The Ahmed® Glaucoma Valve Model FP8 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
Complications and adverse reactions during or following surgery may include:

Corneal Edema	Choroidal detachment
Corneal Touch	Iritis
Iris/Tube Touch	Hyphema
Synechia	Tube Obstruction
Exposed Sclera Graft	Tube Retraction

as well as known complications of aqueous shunts and general intraocular surgery including hypotony, shallow chamber, choroidal effusion, suprachoroidal hemorrhage, retinal detachment, 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.

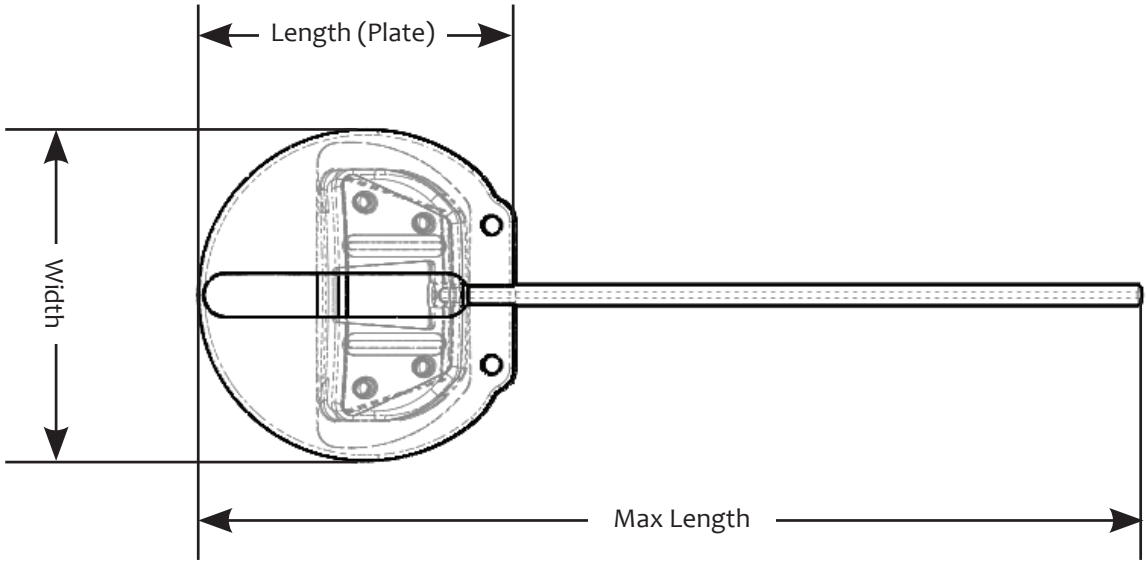
The Ahmed® Glaucoma Valve is intended for single use, it shall not be reused. It shall be discarded to avoid deterioration, cross contamination and/or infection.

Tampering with the valve can cause malfunctioning of the valve.

AGV-FP8

Trade Name: Ahmed® Glaucoma Valve Model FP8

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: 36.4 mm
Plate Length: 11.0 mm
Device Overall Width: 11.0 mm
Drainage Area/Explant Surface Area: 102 mm^2

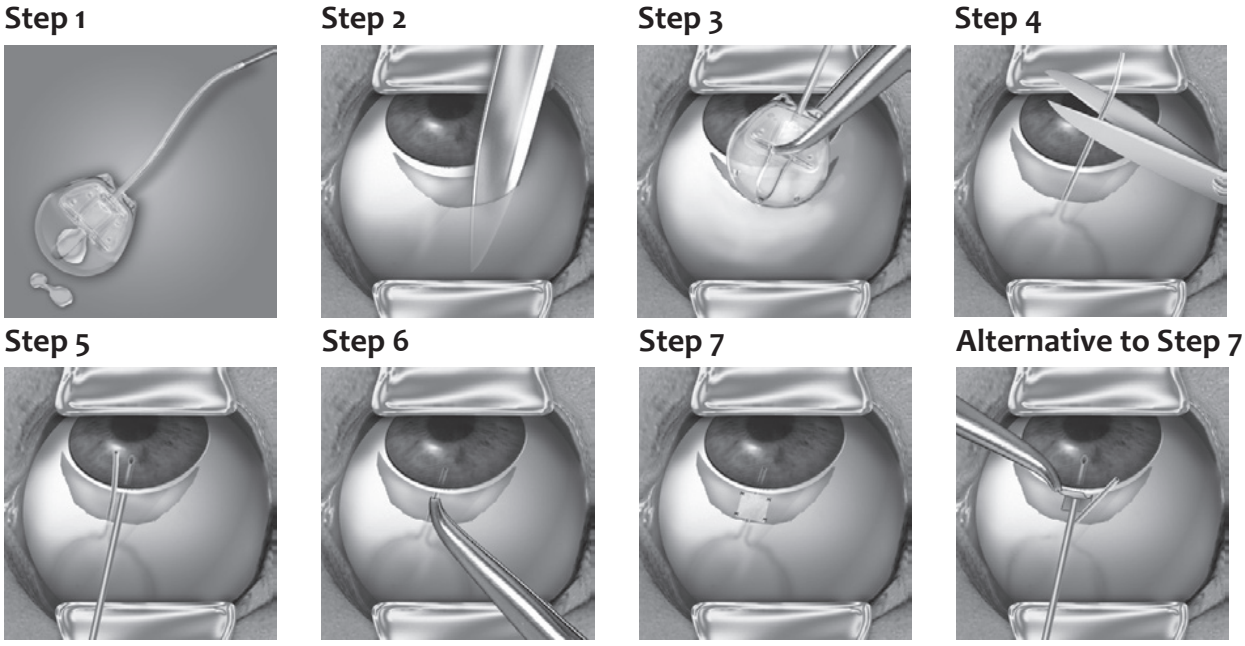
HOW SUPPLIED

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 a 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 a 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 1 mL of balanced salt solution or sterile water through the drainage tube and valve, using a blunt 26-gauge cannula.
2. A conjunctival peritomy incision is made. A pocket is formed superiorly, avoiding the superior rectus and oblique muscles, with 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. Rotate the suture knots into the the suture hole openings. The leading edge of the end plate should be ~ 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. 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. In addition, a paracentesis should be performed to allow for quick AC reformation in case of a flattened AC 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 previously created needle track. The leading edge of the end 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 the use of patch graft material, 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 then sutured closed.

CLINICAL STUDY RESULTS

Published clinical data for the AGV-FP8 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-FP8.

1. Comparison of the Outcome of Silicone Ahmed Glaucoma Valve Implantation with a Surface Area between 96 and 184 mm^2 in Adult Eyes. This study was a retrospective review of records from adult refractory glaucoma patients who underwent either AGV-FP8 or AGV-FP7 implantation by two surgeons at a single center. Similar surgical techniques were used regardless of implant type. Some patients were followed up to 3 years after surgery. There were no statistically significant differences between the groups in preservation of vision, IOP reduction, or decrease in the number of glaucoma medications.

   Koh KM, Hwang YH, Jung JJ, Sohn YH, Kim HK. Comparison of the outcome of silicone Ahmed glaucoma valve implantation with a surface area between 96 and 184 mm^2 in adult eyes. Korean J Ophthalmol. 2013 Oct;27(5):361-7. PubMed PMID: 24082774; PubMed Central PMCID: PMC3782582.

2. Outcomes of Ahmed Valve Implant Following a Failed Initial Trabeculotomy and Trabeculectomy in Refractory Primary Congenital Glaucoma. This was a retrospective noncomparative case series of eyes with a diagnosis of refractory primary congenital glaucoma. The AGV-FP8 was implanted by a single surgeon after a failed primary trabeculectomy + trabeculotomy. In this difficult-to-treat group of patients, the AGV-FP8 was found to be an effective treatment.

   Dave P, Senthil S, Choudhari N, Sekhar GC. Outcomes of Ahmed valve implant following a failed initial trabeculotomy and trabeculectomy in refractory primary congenital glaucoma. Middle East Afr J Ophthalmol. 2015 Jan-Mar;22(1):64-8. PubMed PMID: 25624676; PubMed Central PMCID: PMC4302479.

3. Combined trabeculotomy-trabeculectomy versus Ahmed valve implantation for refractory primary congenital glaucoma in Egyptian patients: a long-term follow-up. This was a randomized, prospective, single-surgeon, comparative study that included 66 eyes with refractory primary congenital glaucoma with up to four years of follow up reported. Patients had previously failed goniotomy and trabeculotomy. Half of the patients underwent a combined trabeculotomy-trabeculectomy procedure and the other half underwent AGV-FP8 implantation. Both procedures were found to be suitable options in advanced refractory primary congenital glaucoma with similar long term IOP reduction, decrease in number of glaucoma medications, and success rates. A higher rate of hyphema was reported in the combined trabeculotomy-trabeculectomy group with other rates of complications similar between the two groups.

   Helmy, Hazem. "Combined trabeculotomy-trabeculectomy versus Ahmed valve implantation for refractory primary congenital glaucoma in Egyptian patients: a long-term follow-up." *Electronic physician* 8.2 (2016): 1884.

4. Surgical outcomes of additional Ahmed glaucoma valve implantation in refractory glaucoma. Clinical histories of 23 refractory glaucoma patients, 21 of whom underwent a AGV-FP8 implantation after a failed glaucoma drainage device implantation were retrospectively reviewed. Outcomes for up to 3 years were reported. Implantation of an AGV-FP8 was described as a good choice for surgical treatment when the first glaucoma drainage device failed. Corneal decompensation was found in some cases but no other serious complications were reported.

   Ko, Sung Ju, et al. "Surgical outcomes of additional Ahmed glaucoma valve implantation in refractory glaucoma." Journal of glaucoma 25.6 (2016): e620-e624.

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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