

The Ahmed® Glaucoma Valve

Patient Information Leaflet



Why is this information necessary?

This Patient Information Leaflet serves to inform patients what to expect regarding the required care, precautions, and follow-up before and after Ahmed® Glaucoma Valve surgery.

What I need to know before glaucoma treatment surgery

What is Glaucoma?

Glaucoma is an eye disease that damages the optic nerve of the eye. If glaucoma is not treated, individuals are at risk of permanent vision loss or blindness. Glaucoma can happen in adults and children, and it can be present since birth or caused by different factors.

What is the Ahmed® Glaucoma Valve & what does it do?

The Ahmed® Glaucoma Valve (Models AGV-FP7 and AGV-FP8) is a valved implant intended to reduce and control eye pressure in patients with advanced glaucoma. The tube drains the fluid out of the eye through the valve, thus reducing eye pressure. The implant is placed outside the eye; however, it is covered by the skin of the eye, so it cannot be seen or felt. What makes the Ahmed® Glaucoma Valve unique is that it has a valve mechanism that reduces the likelihood of lower eye pressures below healthy level, as compared to non-valved glaucoma drainage devices which do not have a built-in valved flow control mechanism.

The Ahmed® Glaucoma Valve includes a silicone plate and a valve mechanism. The valve mechanism is made of a silicone tube and polypropylene body. The polypropylene body houses the silicone elastomer valve membrane to protect it from tissue blockage. The plate fits to the shape of the eye and provides an area where fluid can be dispersed.

What is the Ahmed® Glaucoma Valve used for and when is it recommended?

The Ahmed® Glaucoma Valve is a surgical device that doctors use for people who have a type of glaucoma that has not improved with other treatments.

The Ahmed® Glaucoma Valve is for people with advanced glaucoma that hasn't responded well to other treatments. These people have usually had glaucoma surgery before, are older, and have other health problems that may affect how well the surgery works.

The Ahmed® Glaucoma Valve is used to try and reduce the pressure in the eye so that eyesight can be maintained.

What I need to know after glaucoma treatment surgery

What must I generally be aware of after surgery?

Consult your surgeon for instructions that should be followed starting directly after your surgery. Immediately contact your physician if you experience any allergic reactions and/or adverse effects.

The Ahmed® Glaucoma Valve is comprised of materials with a long history of safe clinical use. Once implanted, it remains permanently in the patient's eye and is expected to be stable over the lifetime of the patient.

It is safe to undergo Magnetic Resonance Imaging (MRI) after treatment with The Ahmed® Glaucoma Valve.

What warnings and precautions should I consider?

Here are some warnings and precautions that you should consider to ensure a safe and successful recovery that you can discuss with your surgeon:

- Avoid activities that could cause strain on your eyes, such as lifting heavy objects, bending, or vigorous

- exercise for several weeks after surgery.
- Avoid rubbing or touching your eyes, as this can damage the implant or increase the risk of infection.
- Use prescribed eye drops as directed by your surgeon to prevent infection and inflammation.
- Attend all follow-up appointments with your eye doctor to monitor your progress and make any necessary adjustments to your treatment plan.
- Be aware of potential signs of infection or complications, such as pain, redness, fever, eye swelling, or vision changes. Contact your doctor immediately if you experience any of these symptoms.
- Avoid swimming, hot tubs, or any other activity that could expose your eyes to water for several weeks after surgery to prevent infection.
- Wear protective eyewear, such as goggles or sunglasses, to shield your eyes from dust, wind, or other irritants.
- Notify your doctor if you experience any sudden changes in vision like cloudiness or severe eye pain, as these may be signs of an implant malfunction or other complications.

Remember, it is essential to follow your doctor's instructions carefully and communicate any concerns or questions you may have about your recovery.

What are the possible risks and potential post-surgery adverse reactions?

Based on the health history of the patient, and the nature of glaucoma drainage device procedures, complications and adverse reactions may occur. After the surgery, your surgeon will examine your eye and will evaluate if any of these potential events or risks are present. Glaucoma surgeons are well trained to treat the various complications that can arise after glaucoma surgery.

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While surgery is generally safe, there are some general possible complications that can occur. These include but are not limited to:

- Bleeding.
- Tube obstruction.
- Device migration.
- Corneal damage.
- Swelling of the iris.

As well as known complications of other types of glaucoma surgery and general eye surgery, such as:

- Low pressure inside the eye.
- Serious infection inside the eye.
- Clouding of the lens inside the eye (cataract).
- Detachment of the retina.
- Inflammation inside the eye.

It's important to note that these complications are relatively rare, and most people who undergo glaucoma implant surgery experience a significant improvement in their condition. However, it's still important to be aware of the risks and to discuss them with your doctor.

Overall benefit-risk evaluation

There is no known cure for glaucoma, and individuals with untreated glaucoma are at risk of permanent vision loss or blindness. Lowering eye pressure is the only adjustable risk factor for minimizing glaucoma progression.

The overall goal of the Ahmed® Glaucoma Valve is the immediate reduction in eye pressure and/or reducing the need for pressure-lowering medications. This clinical benefit may reduce over time due to the natural wound healing around the implant which may restrict fluid to the surrounding tissue.

Most complications and adverse reactions after surgery are not intrinsic to the implant itself but are due to the nature of the surgery and the presence of a foreign body in the eye.

The benefit of preserving vision by using the Ahmed® Glaucoma Valve outweighs the potential complications and adverse reactions, since progression of glaucoma can lead to significant loss of vision and permanent blindness.

Historically, patients who receive the Ahmed® Glaucoma Valve have shown immediate improvement and reduction in eye pressure after surgery. The Ahmed® Glaucoma Valve flow control mechanism has been shown to maintain eye pressure within healthy levels and has success at preventing eye pressures from dropping below normal limits.

There is no single target eye pressure that is appropriate for every patient; target pressure needs to be estimated separately for each eye and adapted to changing patient conditions. Talk to your doctor to establish the eye pressure target suitable for you; this target pressure may be updated at each monitoring visit based on changes in your medical condition. New World Medical has considered and mitigated as far as possible all significant risks and deemed them acceptable.

Further Information:

Contents: The valve mechanism is comprised of a silicone drainage tube and polypropylene body which houses a silicone elastomer valve membrane.

Model: AGV-FP7, AGV-FP8

Please refer to our patient Implant Card for the model number of your implant.

Therapeutic Goods Administration:

Any serious incident that occurs in relation to the device should be reported directly to the local representative or the manufacturer at the email address surveillance@newworldmedical.com, as well as the Therapeutic Goods Administration at www.tga.gov.au

European Union Member States:

For customers from countries within the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Manufacturer:

New World Medical, Inc.
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U.S.A
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