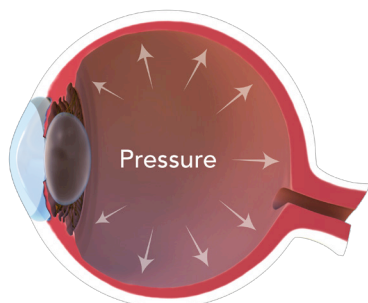




WHAT IS GLAUCOMA?

GLAUCOMA IS A GROUP OF DISEASES OF THE EYE THAT, LEFT UNTREATED, CAN IMPAIR VISION AND EVEN CAUSE BLINDNESS.

A major risk factor for glaucoma is increased eye pressure that occurs when fluid (aqueous) in the eye – used to transport important nutrients to the lens – accumulates and cannot drain naturally.



Over time the trapped fluid builds up, causing pressure in the eye, which can damage the optic nerve and destroy vision.

Glaucoma can be grouped into two categories:

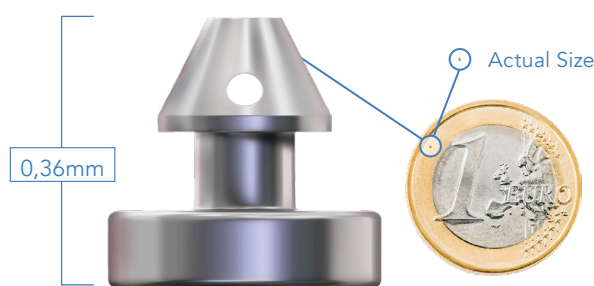
- Open-angle glaucoma: accounts for approximately 70% to 90% of all cases. Open-angle glaucoma is asymptomatic – meaning it occurs without noticeable symptoms appearing – and can often go undiagnosed without proper check-ups, and worsen over time; and
- Angle-closure glaucoma: less common but more severe, and is marked by a rapid rise in eye pressure and severe vision loss.

The first sign of glaucoma is often loss of peripheral or side vision. Untreated glaucoma can lead to tunnel vision, and eventually can cause total blindness.



WHAT IS THE iStent *inject*® W?

iStent *inject*® W is one of the smallest medical devices known to be implanted in the human body. iStent *inject*® W measures just 0.36mm long and is made of titanium.



The iStent *inject*® W



71%
medication
reduction¹

WHO IS SUITABLE FOR THE iStent *inject*[®] W ?

The iStent *inject*[®] W Trabecular Micro-Bypass System is designed to reduce intraocular pressure safely and effectively in patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma.

Studies have shown the iStent[®] technology to be safe and effective when implanted in combination with cataract surgery, or as a stand-alone procedure, in those patients who require intraocular pressure reduction and/or would benefit from glaucoma medication reduction.² The device may also be implanted in patients who continue to have elevated intraocular pressure despite prior treatment with glaucoma medications and conventional glaucoma surgery.

HOW DOES IT WORK?

Implanted at the time of cataract surgery, or in a separate procedure, iStent *inject*[®] W is designed to create a bypass between the front part of the eye and its natural drainage pathway to increase the flow of fluid. By creating a permanent bypass through the primary blockage site (trabecular meshwork), iStent *inject*[®] W is designed to a) improve the eye's natural fluid outflow to safely lower intraocular pressure, and b) work continuously to improve the natural flow of fluid in the eye.

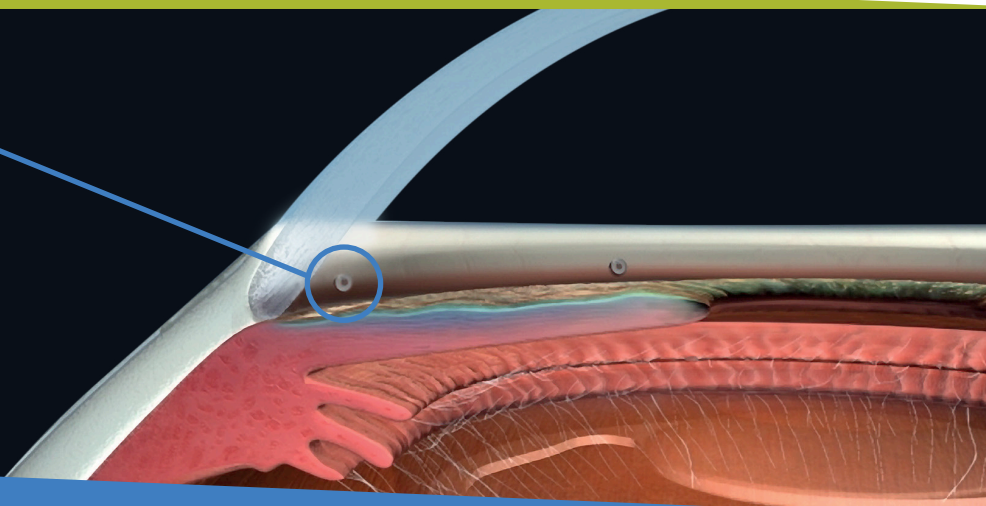
WHAT ARE THE BENEFITS OF IMPLANTING AN iStent *inject*[®] W?

The iStent *inject*[®] W Trabecular Micro-Bypass System is designed to lower eye pressure and reduce the risk of vision loss from glaucoma. It may also reduce or remove the number of glaucoma eye drops you might be using now, at the direction of your physician, preserving your eye tissues and anatomy.

An international study including patients treated with iStent *inject*[®] procedures with a high preoperative glaucoma treatment burden shown 71% medication reduction at 5 years.¹



The iStent
inject[®] W



WHAT DOES THE OPERATION INVOLVE?

The operation is usually performed under a local anaesthetic, meaning that you are awake but your eye is numb so you will not feel anything.

The iStent *inject*[®] W Trabecular Micro-Bypass System is implanted through a small, self-sealing incision in the clear part of the eye (cornea) using a small injector, and can be performed at the same time as a cataract surgery or by itself. Once implanted, the iStent *inject*[®] W Trabecular Micro-Bypass System is designed to work immediately.

At the end of the procedure, your operated eye will often be covered with a pad and/or protective shield, which you might also be instructed to wear at night for a few days as a precautionary safety measure to protect your eye.

iStent *inject*[®] W Trabecular Micro-Bypass System surgery and cataract surgery is usually completed as a day case, meaning that you should be able to go home the same day, but you will not be able to drive so you are advised to have someone collect you from the hospital or clinic.



HOW SOON WILL I RECOVER?

Immediately after the procedure your vision in the operated eye might be blurry for one to two weeks, and your eye might be slightly bloodshot for a few days.

You will be prescribed antibiotic and anti-inflammatory eye drops to prevent infection and inflammation, which you should take as prescribed.

Your eye doctor will inform you if or when you can stop taking any glaucoma eye drops. Do not stop taking your drops in either eye, unless specifically instructed to do so by your eye doctor.



WHAT ARE THE RISKS?

The iStent *inject*[®] W is indicated to reduce eye pressure in patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma, or pigmentary glaucoma. It can be implanted as a standalone surgery or in combination with cataract surgery.

The iStent *inject*[®] W can also be implanted in patients who would benefit from fewer eye drops or who have previously had glaucoma surgery. The iStent *inject*[®] W should not be used to treat those with closed-angle glaucoma, glaucoma due

to new eye vessels, or in patients with thyroid eye disease, certain eye tumors or nerve conditions. After iStent *inject*[®] W implantation, some patients have experienced inflammation and swelling of the eye, decreased vision sharpness, cloudiness, and stent obstruction.

Please refer to the iStent *inject*[®] W product labeling for additional safety information, or visit www.glaukos.com. iStent *inject*[®] W can only be sold by, or ordered by a physician. Please consult your ophthalmologist to see if iStent *inject*[®] W is right for you.

RISK FACTORS

Glaucoma is believed to be a genetic disease and may not appear until later in life. Besides hereditary factors, glaucoma can also be caused by a severe eye infection, a blunt eye injury or trauma, inflammatory eye conditions, or blockage of the eye's blood vessels.

RISK FACTORS MAY INCLUDE:

- Elevated eye pressure
- Having a relative with glaucoma
- Sudden considerable changes in eye pressure
- Decreased central corneal thickness
- Older age
- Blunt eye trauma
- African, Asian or Hispanic ethnicity
- Inflammatory eye conditions

DEFINITION OF EYE WORDS

Aqueous: A clear fluid that circulates inside the front portion of the eye.

Cataract: A clouding of the lens in the eye which leads to a decrease in vision.

Cornea: A clear, dome-shaped window at the front of the eye.

Glaucoma: A condition that damages the optic nerve of the eye, often associated with high eye pressure.

Intraocular Pressure: The fluid pressure inside the eye.

Iris: The coloured part of the eye that controls the size of the pupil.

Optic Nerve: Transmits visual information from the retina to the brain.

Pupil: The opening at the centre of the iris.

Schlemm's Canal: A circular canal into which aqueous drains after passing through the trabecular meshwork.

Trabecular Meshwork: A sieve-like meshwork through which aqueous drains before entering Schlemm's canal.

REFERENCES:

- 1- Hengerer, Fritz H., Gerd U. Auffarth, and Ina Conrad-Hengerer. "iStent *inject* Trabecular Micro-Bypass with or Without Cataract Surgery Yields Sustained 5-Year Glaucoma Control." *Advances in Therapy* (2022): 1-15
- 2- Voskanyan L, Garcia-Feijó J, Belda J, Fea A, Jünemann A, Baudouin C. Prospective, unmasked evaluation of the iStent *inject*[®] system for open-angle glaucoma: Synergy trial. *Adv Ther.* 2014;31:189–201.



iStent *inject*[®] W IMPORTANT SAFETY INFORMATION

INDICATION FOR USE: The iStent *inject*[®] W, is intended to reduce intraocular pressure safely and effectively in patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma. The iStent *inject*[®] W, can deliver two (2) stents on a single pass, through a single incision. The implant is designed to stent open a passage through the trabecular meshwork to allow for an increase in the facility of outflow and a subsequent reduction in intraocular pressure. The device is safe and effective when implanted in combination with cataract surgery in those subjects who require intraocular pressure reduction and/or would benefit from glaucoma medication reduction. The device may also be implanted in patients who continue to have elevated intraocular pressure despite prior treatment with glaucoma medications and conventional glaucoma surgery. **CONTRAINDICATIONS:** The iStent *inject*[®] W System is contraindicated under the following circumstances or conditions: In eyes with primary angle closure glaucoma, or secondary angle-closure glaucoma, including neovascular glaucoma, because the device would not be expected to work in such situations. In patients with retrolbulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. **WARNINGS/PRECAUTIONS:** For prescription use only. This device has not been studied in patients with uveitic glaucoma. Do not use the device if the Tyvek® lid has been opened or the packaging appears damaged. In such cases, the sterility of the device may be compromised. Due to the sharpness of certain injector components (i.e. the insertion sleeve and trocar), care should be exercised to grasp the injector body. Dispose of device in a sharps container. iStent *inject*[®] W is MR-Conditional; see MRI Information below. Physician training is required prior to use of the iStent *inject*[®] W System. Do not re-use the stent(s) or injector, as this may result in infection and/or intraocular inflammation, as well as occurrence of potential postoperative adverse events as shown below under "Potential Complications." There are no known compatibility issues with the iStent *inject*[®] W and other intraoperative devices. (e.g., viscoelastics) or glaucoma medications. Unused product & packaging may be disposed of in accordance with facility procedures. Implanted medical devices and contaminated products must be disposed of as medical waste. The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. If intraocular pressure is not adequately maintained after surgery, the surgeon should consider an appropriate treatment regimen to reduce intraocular pressure. Patients should be informed that placement of the stents, without concomitant cataract surgery in phakic patients, can enhance the formation or progression of cataract. **ADVERSE EVENTS:** Please refer to Directions For Use for additional adverse event information. **CAUTION:** Please reference the Directions For Use labelling for a complete list of contraindications, warnings and adverse events.