



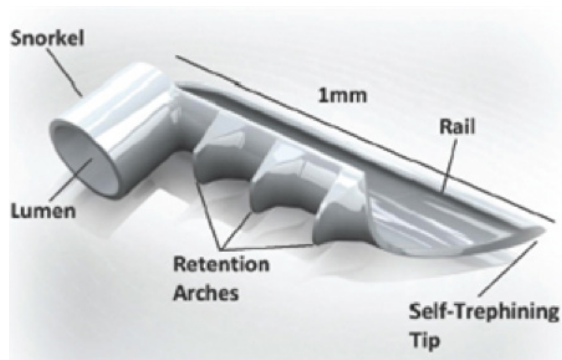
iStent Trabecular Micro-Bypass Stent

iStent Trabecular Micro-Bypass Stent

What is the iStent Trabecular Micro-Bypass Stent?

The iStent Trabecular Micro-Bypass Stent is a L-shaped stent which is only 1.0mm long and is made of lightweight titanium (Figure 1). It is so small that you will not see or feel it.

A.



B.

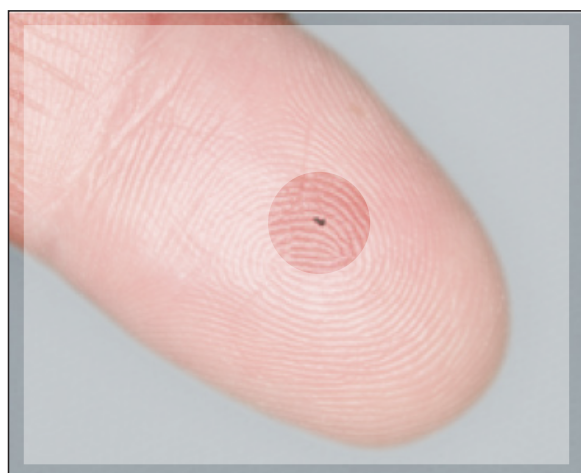


Figure 1.

(A) A magnified illustration of an iStent
(B) The real size of an iStent in comparison with a fingertip (Courtesy of Glaukos Corp, California, United States)

The iStent Trabecular Micro-Bypass Stent is inserted into the natural drainage canal of the eye (Figure 2), bypassing the trabecular meshwork, which is a structure that drains fluid from the eye and is often obstructed in patients with glaucoma. Glaucoma is a disease in which the pressure within the eye builds up and damages the eye nerve. Treatment of glaucoma involves lowering the eye pressure.

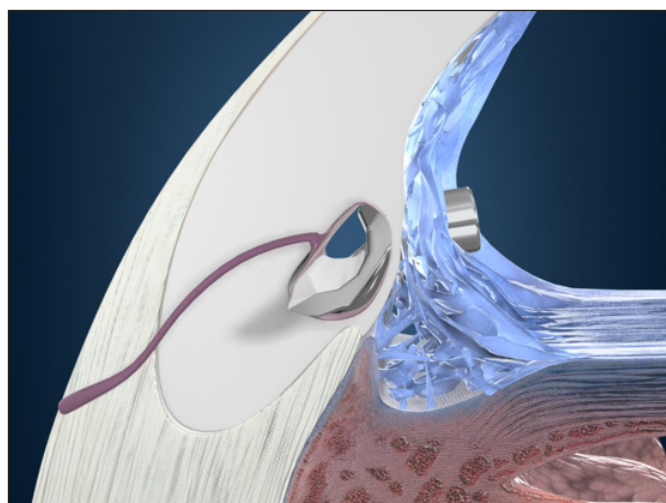


Figure 2.

Illustration showing the iStent Trabecular Micro-Bypass Stent in the natural drainage canal of the eye (Courtesy of Glaukos Corp, California, United States)

The iStent Trabecular Micro-Bypass Stent is permanent and is well-accepted by the body. It will stay in the eye to drain fluid from the eye (Figure 3). This reduces the pressure in the eye hence slows down glaucoma progression and preserves the vision.

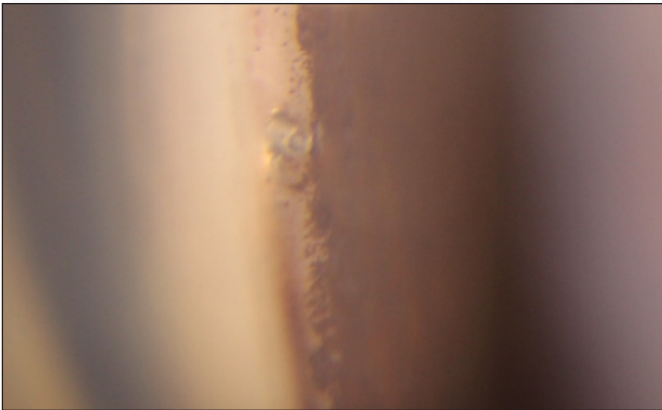


Figure 3.
Photograph showing an iStent Trabecular Micro-Bypass Stent in the natural drainage canal of the eye (Courtesy of Chelvin Sng)

If you are scheduled for magnetic resonance imaging (MRI) after iStent Trabecular Micro-Bypass Stent insertion, you would need to inform your doctor that you have an iStent in your eye. You can still undergo MRI safely in a specified MR environment under specified conditions (this information can be obtained from your eye doctor). Because of the very small dimensions of the iStent, heating and artifacts will not pose a problem or added risk for MRI under these specified conditions.

The iStent Trabecular Micro-Bypass Stent is most often used in patients with mild and moderate open angle glaucoma who wish to reduce the number of glaucoma medications required. Patients usually choose to have the iStent Trabecular Micro-Bypass Stent inserted at the same time as cataract surgery, though some undergo iStent surgery by itself. If you have very advanced glaucoma, the iStent Trabecular Micro-Bypass Stent is unlikely to lower your eye pressure sufficiently.

The iStent Trabecular Micro-Bypass Stent will not reverse any damage already caused by glaucoma, improve your vision or cure your glaucoma.

What are the advantages of the iStent Trabecular Micro-Bypass Stent?

The iStent Trabecular Micro-Bypass Stent is less invasive compared with other conventional glaucoma surgeries (such as trabeculectomy or tube shunt implants). Only a very small cut in the eye is required to insert the iStent Trabecular Micro-Bypass Stent and unlike conventional glaucoma surgeries, stitches are usually not required. Hence, the surgery is faster and more straightforward with a quicker recovery time. Unlike conventional glaucoma surgeries, the iStent Trabecular Micro-Bypass Stent is unlikely to have much effect on your spectacles power.

The iStent Trabecular Micro-Bypass Stent has an excellent safety profile, with much less complications reported compared with conventional glaucoma surgeries. In particular, the rate of sight-threatening complications (eg. major bleeds at the back of the eye, infection) are extremely rare. The safety profile of iStent Trabecular Micro-Bypass Stent surgery is similar to that of cataract surgery alone. If subsequent conventional glaucoma surgery is required after iStent Trabecular Micro-Bypass Stent surgery, they can still be performed and the iStent would not make subsequent conventional surgeries less effective.

In previous clinical studies, the iStent Trabecular Micro-Bypass Stent usually lowers eye pressure to the mid-to-high teens and reduces the number of glaucoma medications by approximately one.¹⁻³ Of course, results may vary between different patients.

How is the iStent Trabecular Micro-Bypass Stent inserted into the eye?

The iStent Trabecular Micro-Bypass Stent can be inserted into the eye either at the same time as cataract surgery or by itself. Eyedrops are used to make the eye numb and some surgeons may also give an injection around the eye so that you won't feel pain or discomfort during the procedure. In some hospitals, you may also receive light sedation during the surgery so that you will feel more relaxed and comfortable. You will be awake during the procedure and should not feel any pain during the surgery.

Only a very small cut in the eye is required to insert the iStent Trabecular Micro-Bypass Stent, which does not require stitches (Figure 4). More than one iStent Trabecular Micro-Bypass Stents may be inserted into your eye during the surgery, and two iStents have been shown to be more effective than one iStent.² The procedure usually takes approximately 5 to 10 minutes. At the end of the procedure, the operated eye is covered with an eye shield and may also be padded. You will usually be able to go home the same day as your operation.

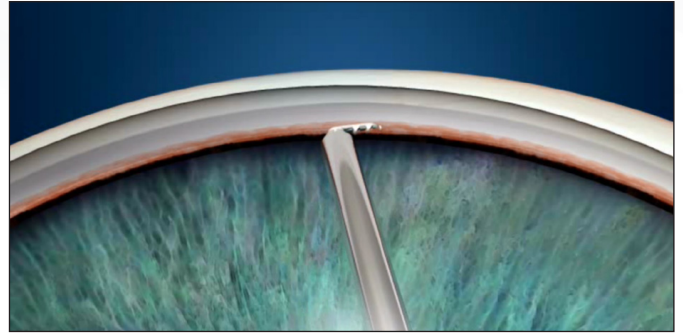


Figure 4.

The iStent Trabecular Micro-Bypass Stent is introduced into the eye through a very small cut and inserted into the natural drainage canal of the eye (Courtesy of Glaukos Corp, California, United States)

What precautions should I take after undergoing iStent Trabecular Micro-Bypass Stent surgery?

You should avoid strenuous activities for the first month, including swimming, jogging, contact sports and vigorous exercises. It would be advisable to cover the operated eye with an eye shield at night for a few weeks after the surgery, so as to avoid accidental injury to the eye while you are sleeping. Eye make-up should be avoided for about 4 weeks after the surgery. Reading or watching the television will not harm your eye and you may continue with these activities as usual.

Your doctor will prescribe you with antibiotic and anti-inflammatory eyedrops. Immediately after the surgery, you may still need to continue the glaucoma eyedrops in the operated eye. It is important to use these eyedrops as instructed by your eye doctor. If your other eye requires glaucoma eyedrops

as well, they will still need to be continued as usual after the surgery.

The nature of your work will determine the length of time you would need to take off work after the surgery, though most people take two to three weeks off.

What are the risks associated with the iStent Trabecular Micro-Bypass Stent?

The iStent Trabecular Micro-Bypass Stent has an excellent safety profile, with the rate of complications similar to cataract surgery alone.²⁻³

During the surgery

There is a small risk of damage to the other structures in the eye during the surgery, such as the iris (the structure made of muscle which controls the size of your pupil and is in front of the lens) and the cornea (the transparent structure in front of the eye which allows light into the eye). If you are not undergoing cataract surgery at the same time, there is also a potential risk of the surgery damaging your lens and causing a cataract. Bleeding in the front of your eye may occur during the surgery, which usually resolves on its own within two weeks after the surgery. Depending on the structure of your eye, it may not be possible to implant the iStent Trabecular Micro-Bypass Stents in some eyes.

After the surgery

The most common complication after the surgery is bleeding in the front of your eye,

which usually resolves on its own within two weeks after the surgery. Occasionally, the iStent Trabecular Micro-Bypass Stent may become blocked by iris, and an additional laser procedure may be necessary to relieve this blockage. Another very rare complication is dislodgement of the iStent Trabecular Micro-Bypass Stent, which may require a second surgery to re-position the iStent.

If your eye pressure is still not low enough after iStent Trabecular Micro-Bypass Stent surgery, your glaucoma may progress and you may need to re-start your glaucoma medications or further surgeries may be required to control your eye pressure. The iStent Trabecular Micro-Bypass Stent would not make subsequent conventional glaucoma surgeries less effective.

Serious complications after iStent Trabecular Micro-Bypass Stent surgery (e.g. vision loss, major bleeds at the back of the eye, infection, detachment of the retina [light-sensitive tissue lining the back of the eye]) are fortunately extremely rare. However, every time you undergo an eye surgery, these serious complications can potentially occur, though the risk of these occurring with the iStent Trabecular Micro-Bypass Stent is significantly less than that associated with conventional glaucoma surgeries.²⁻³

What are the alternatives to the iStent Trabecular Micro-Bypass Stent?

Glaucoma can be treated with medications to lower the pressure in the eye. However, many

patients do not use glaucoma medications as regularly as they should, experience side effects from the medications or are allergic to them. The medications may also not reduce the eye pressure sufficiently, and surgical procedures may be required to control the eye pressure and prevent further vision loss from glaucoma.

A laser procedure called selective laser trabeculoplasty may be appropriate for some patients with open angle glaucoma,

though in other patients it may not reduce the eye pressure sufficiently or may need to be repeated. Conventional glaucoma surgeries include trabeculectomy or tube shunt implants, which are effective in lowering the eye pressure but are associated with potentially serious complications. Besides the iStent Trabecular Micro-Bypass Stent, other minimally invasive glaucoma surgery devices are also available. Please consult your eye doctor regarding the most appropriate surgery or glaucoma device for you.

References

1. Sng CCA, Harasymowycz P, Barton K. Microinvasive glaucoma surgery. J Ophthalmol 2017;2017:9845018.
2. Chen DZ, Sng CCA. Safety and efficacy of microinvasive glaucoma surgery. J Ophthalmol 2017;2017:3182935.
3. Kerr NM, Wang J, Barton K. Minimally invasive glaucoma surgery as primary stand-alone surgery for glaucoma. Clin Exp Ophthalmol 2017;45:393-400.

This patient information leaflet is prepared by the APGS - MIGS Interest Group:

Members

Norman Aquino, Philippines
Nafees Begum Baig, Hong Kong
Poemen Chan, Hong Kong
Tanuj Dada, India
Seng Kheong Fang, Malaysia
Paul Healey, Australia
Nazrul Islam, Bangladesh
Catherine Liu, Taiwan
Da Wen Lu, Taiwan
Prin Rojanapongpun, Thailand
Clement Tham, Hong Kong
Ningli Wang, China
Xiulan Zhang, China

Convenor

Chelvin Sng, Singapore

Disclaimer

This information leaflet contains general information about the iStent Trabecular Micro-Bypass Stent. The information is not advice and should not be treated as such. The medical information is provided without representations or warranties, express or implied. You must not rely on the information in this leaflet as an alternative to medical advice from your eye doctor. If you have any specific questions, you should consult your eye doctor. You should never delay seeking medical advice, disregard medical advice or discontinue medical treatment because of information on this leaflet.