



PreserFlo MicroShunt

PreserFlo MicroShunt

What is the PreserFlo MicroShunt?

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. The PreserFlo MicroShunt is a very small 8.5 mm tube. It is so small that it can only be seen well using a microscope, such as the slit lamp in the clinic. (Figure 1). It is made of a material called SIBS. SIBS is very flexible, soft, very thin, and tolerated well when implanted in tissues for other medical uses, such as a coating in bypass stents.

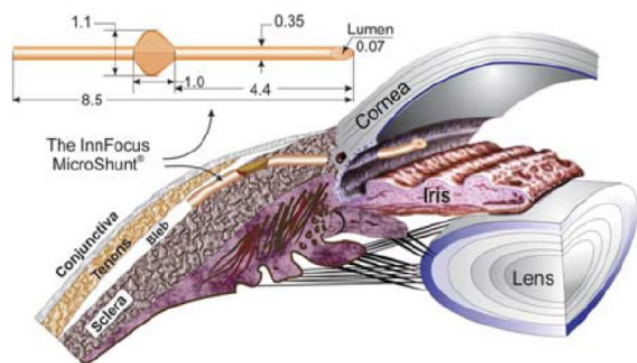
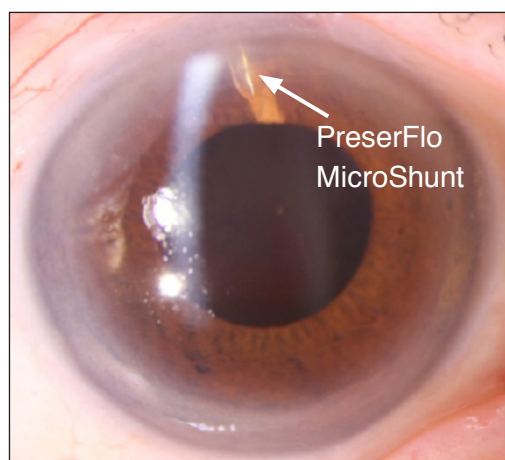


Figure 1. Dimensions (mm) of the PreserFlo MicroShunt and its location within the eye. (Courtesy of Santen Inc., California, USA)

The PreserFlo MicroShunt is placed in your eye to make a new permanent pathway to drain fluid from the eye to a small pocket of fluid (bleb) under the most superficial layer of the eye (conjunctiva) (Figure 2). This helps

preserve your vision by reducing the pressure in your eye and slowing down glaucoma progression.

A.



B.

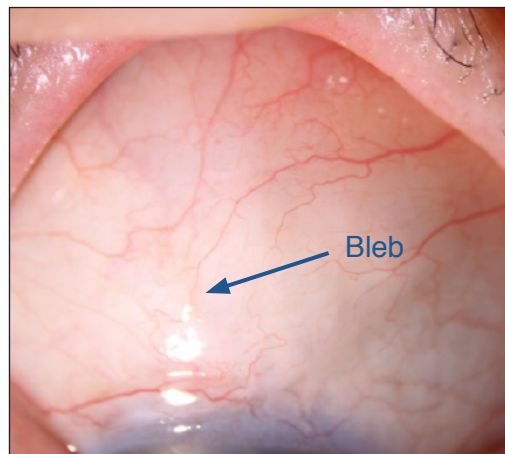


Figure 2. Photograph showing an PreserFlo MicroShunt in the front of the eye (A). The PreserFlo MicroShunt drains fluid from the eye to a bleb (B) (Courtesy of Chelvin Sng)

The PreserFlo MicroShunt is most often used in patients with open angle glaucoma whose

eye pressure is not sufficiently reduced by eye drops or laser. Patients who do not use glaucoma medications as regularly as they should, experience side effects from the medications or are allergic to them may also choose to have the PreserFlo MicroShunt inserted by itself or in combination with cataract surgery, so as reduce the number of glaucoma medications required.

The PreserFlo MicroShunt will not reverse any damage already caused by glaucoma, improve your vision or cure your glaucoma.

What are the advantages of the PreserFlo MicroShunt?

The PreserFlo MicroShunt is less invasive than trabeculectomy, a conventional glaucoma surgery, and involves less cutting and removal of eye tissue. The procedure is shorter and easier to perform than trabeculectomy. The PreserFlo MicroShunt has a good safety profile. There is an intrinsic resistance to fluid flow through the PreserFlo MicroShunt, so the eye pressure obtained in the first few days after surgery is more predictable as compared with trabeculectomy. There is an ongoing study comparing the efficacy of the PreserFlo MicroShunt with trabeculectomy, and preliminary results suggest that the MicroShunt is associated with less complications compared with trabeculectomy, though trabeculectomy attains lower eye pressure.¹⁻³

How is the PreserFlo MicroShunt inserted into the eye?

The procedure to insert the PreserFlo

MicroShunt takes less time and involves less cutting of eye tissues than conventional glaucoma surgery, such as trabeculectomy. If you have cataracts, the PreserFlo MicroShunt can also be safely implanted during cataract surgery. First, your surgeon will give you an injection to numb your eye. In some hospitals, you may also receive light sedation during the surgery so that you will feel more relaxed and comfortable.

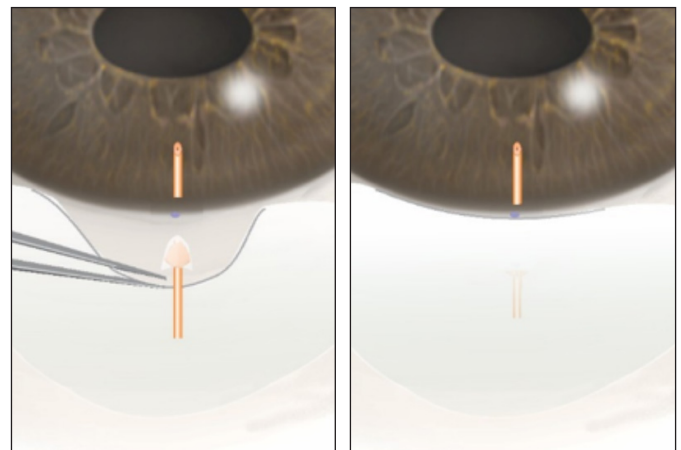


Figure 3.

- A. The PreserFlo MicroShunt is inserted into the eye after opening up the conjunctiva
 - B. After insertion of the PreserFlo MicroShunt, the conjunctiva is closed with stitches
- (Courtesy of Santen Inc., California, USA)*

During the surgery, the conjunctiva (most superficial layer of the eye covering the white part of the eye) will be opened. A medication called mitomycin C is given to your eye, which reduces scarring and increases the long-term success of your surgery, then the PreserFlo MicroShunt is inserted into your eye. The conjunctiva is then closed with stitches (Figure 3). You will be awake during the procedure and should not feel any pain during the implantation. The procedure usually takes approximately 20 - 30 minutes.

After 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. You will be given eye drops that will help the healing process. Use these drops according to your surgeon's instructions.

What precautions should I take after undergoing PreserFlo MicroShunt 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 eyedrops to prevent infection, and anti-inflammatory eyedrops to minimize scarring and increase the long-term success of the surgery. It is important to use these eyedrops as instructed by your eye doctor. The anti-inflammatory eyedrop may need to be continued for several months after the surgery, and only stop it if your eye doctor has explicitly asked you to do so. Immediately after the surgery, you will be asked to stop using the glaucoma eyedrops in the operated eye as the PreserFlo MicroShunt works immediately to lower your eye pressure. 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 four weeks off.

What are the risks associated with the PreserFlo MicroShunt?

Studies have shown that the PreserFlo MicroShunt has a good safety profile.

However, there are still potential complications associated with the surgery:

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). 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 is usually minor and resolves on its own within a few weeks after the surgery. If there is bleeding inside your eye, your vision may be blurred for a few weeks.

After the surgery

Bleeding can occur in the front of your eye after the surgery, which usually resolves on its own within a few weeks. There is also a small risk of the eye pressure being too low after PreserFlo MicroShunt surgery, and this resolves within 3 months in the vast majority of cases. Your vision may be blurred when the

eye pressure is low, but it usually improves to baseline when the eye pressure increases within 3 months. Low eye pressure can occasionally be due to the leakage of fluid from the bleb. Low eye pressure can lead to an accumulation of fluid in the wall of the eye (choroidal detachment) but this usually resolves spontaneously when the eye pressure increases. Rarely, if the eye pressure is low for a prolonged period of time or if the front section of your eye is flat in association with low eye pressure, you may require an injection of a jelly-like substance (called viscoelastic) into the front section of your eye. This is usually performed in the clinic. Rarely, you may require another surgery to address the low eye pressure.

If scarring occurs around the PreserFlo MicroShunt, fluid will not flow well from the implant. Additional procedures may be required to break the scar tissue after the implant, which are usually performed in the clinic but may require another surgery. Very rarely, the PreserFlo MicroShunt may also be blocked (e.g. by iris, inflammatory material or blood), and additional laser or surgical procedures may be necessary to relieve this blockage. If your eye pressure is still not low enough after PreserFlo MicroShunt 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. High eye pressure may lead to glaucoma progression if left untreated.

Unlike conventional tube implant surgery, the PreserFlo Microshunt is smaller and made of a different material, hence is less likely to damage the cornea (the transparent structure in front of the eye). Erosion of the conjunctiva

covering the PreserFlo MicroShunt has not been reported and is much less likely compared with erosion of the conjunctiva covering a conventional tube implant. Migration of the PreserFlo MicroShunt after the surgery has not been observed previously. However, these complications (cornea damage, conjunctiva erosion and PreserFlo MicroShunt migration) are still potentially possible.

Rarely, a small number of patients may experience increased eye dryness or discomfort due to the presence of the bleb. Most of the time, these symptoms are relieved by lubricating eyedrops. However, if the discomfort persists, additional steps may need to be taken to make the bleb more comfortable. As with conventional glaucoma surgery, it is also possible that the eyelids may become more droopy after PreserFlo MicroShunt surgery. If your cataract has not been removed, the cataract may become worse after PreserFlo MicroShunt surgery, resulting in a decrease in vision. If this occurs, you may require subsequent cataract surgery.

Serious complications after PreserFlo MicroShunt 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 PreserFlo MicroShunt is likely to be less than that associated with conventional glaucoma surgeries.²⁻³ All surgeries which create blebs have a potential life-long risk of infection.

What are the alternatives to the PreserFlo MicroShunt?

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 PreserFlo MicroShunt, 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 PreserFlo MicroShunt. 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.