

# PRESERFLO™ MicroShunt

A simpler way to manage your glaucoma

This guide will provide information on how **PRESERFLO™ MicroShunt** helps treat glaucoma and what to expect before, during, and after surgery.





## Benefits of PRESERFLO™ MicroShunt



### Designed to Lower Eye Pressure

PRESERFLO™ MicroShunt is designed to drain excess fluid from your eye, which may lower eye pressure and prevent further vision loss.



### Fewer Complications

Compared with traditional glaucoma surgeries, PRESERFLO™ MicroShunt may result in fewer complications after surgery.

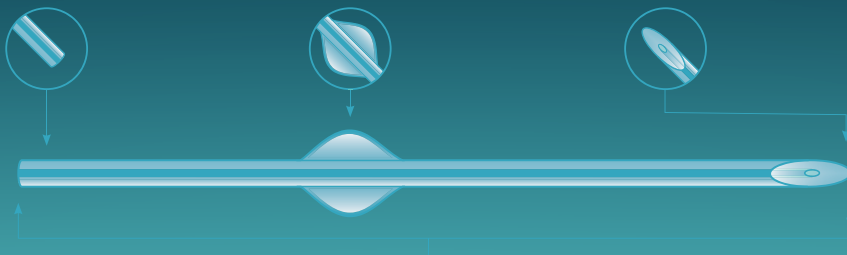


Always consult your surgeon about any changes to medications or lifestyle that may affect your eyesight after surgery.



## Fewer Medications

In the pivotal study, the majority of PRESERFLO™ MicroShunt patients were medication-free at 12 months.<sup>1</sup> Medication reduction is at the discretion of your physician.



# Understanding PRESERFLO™ MicroShunt



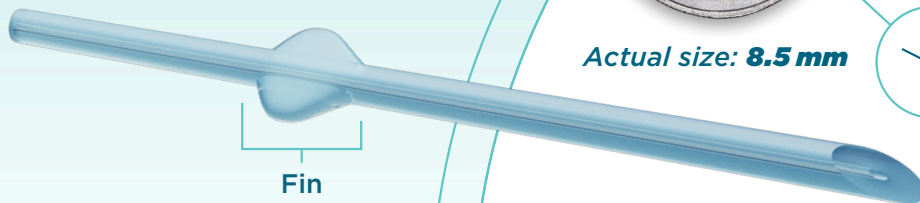
## Why am I getting PRESERFLO™ MicroShunt?

Normally, fluid is circulated in the eye to maintain healthy ocular pressure. If fluid does not drain properly, it builds up and raises the pressure inside your eye. This may damage the delicate tissues around it, potentially leading to permanent vision loss.

PRESERFLO™ MicroShunt is a tiny, soft, flexible stent that helps your eye drain excess fluid, may lower eye pressure, and prevent further vision loss. PRESERFLO™ MicroShunt will not restore vision already lost to glaucoma.



**Actual size: 8.5 mm**





## What happens **BEFORE** surgery?

To prepare for surgery, your surgeon may instruct you to stop taking your usual medications or to begin taking new ones. Be sure to follow instructions accurately and discuss associated risks, safety information, and questions you may have prior to surgery.

For your safety, arrange to have someone take you home after surgery.

Important Safety Information is found on the back cover of this brochure.



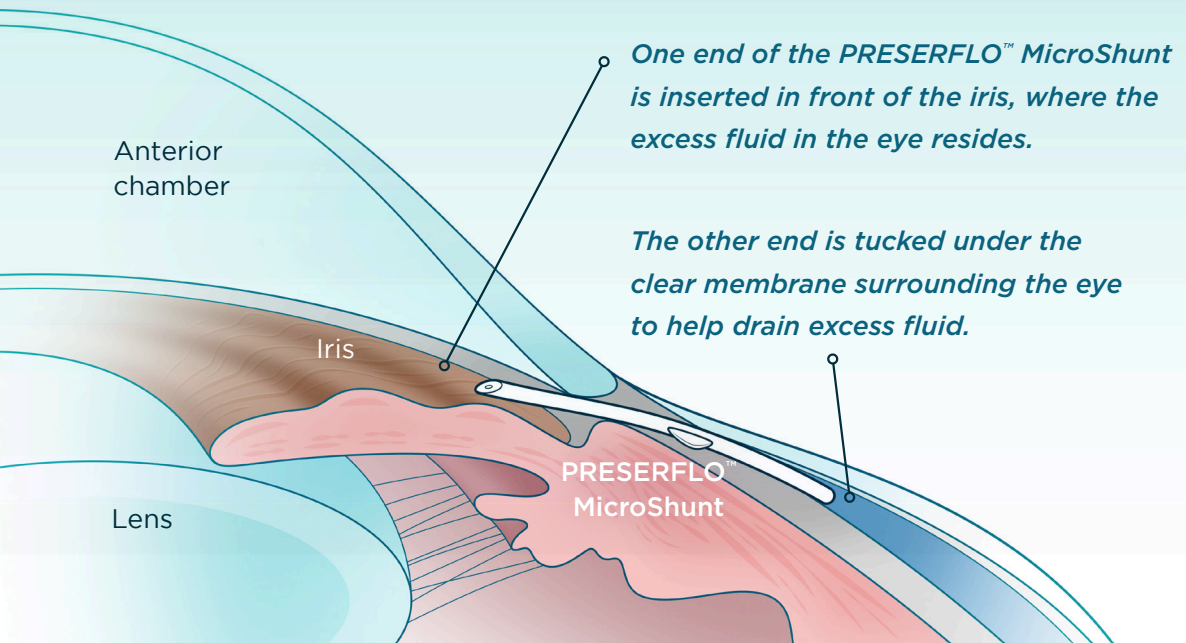


## How does PRESERFLO™ MicroShunt work?

PRESERFLO™ MicroShunt is a permanent treatment option for the management of glaucoma to help drain excess fluid out of the eye.

PRESERFLO™ MicroShunt is implanted during an outpatient surgical procedure under anesthesia. The procedure is less invasive than traditional glaucoma surgeries and may take less time to complete.

Its size, shape, and fin help keep the PRESERFLO™ MicroShunt stable and securely in place, and it is designed to resist degradation over time.<sup>2</sup>







## What happens **AFTER** surgery?

In the first week after surgery, you may experience symptoms including:



**Blurry vision**



**Eye redness**



**Eye swelling**

These symptoms should go away.

To help the recovery process, your surgeon may prescribe eye drops. Do not rub your eye or perform any strenuous activity, including sports, shortly after surgery.



Contact your surgeon immediately if blurriness, redness, or pain persists.



**REFERENCES:** 1. Baker D, Barneby H, Moster M, et al. Ab-Externo MicroShunt versus Trabeculectomy in Primary Open-Angle Glaucoma. *Ophthalmology*. May 2021, doi: <https://doi.org/10.1016/j.ophtha.2021.05.023> 2. Pinchuk L, Riss I, Batlle JF, Kato Y, Martin JB, et al. The use of poly(styrene-*block*-isobutylene-*block*-styrene) as a microshunt to treat glaucoma. *Regenerative Biomaterials*. 2016;3(2):137-142.

#### IMPORTANT SAFETY INFORMATION

**INDICATION FOR USE.** The PRESERFLO™ MicroShunt Glaucoma Drainage System is intended for reduction of intraocular pressure in eyes of patients with primary open angle glaucoma where IOP remains uncontrollable while on maximum tolerated medical therapy and/or where glaucoma progression warrants surgery. **CONTRAINDICATIONS.** The implantation of the PRESERFLO™ MicroShunt is contraindicated if one or more of the following conditions exist: Bacterial Conjunctivitis; Bacterial Corneal Ulcers; Endophthalmitis; Orbital Cellulitis; Bacteremia or Septicemia; Active Scleritis; Uveitis; Severe Dry Eye; Severe Blepharitis; Pre-existing ocular or systemic pathology that, in the opinion of the surgeon, is likely to cause postoperative complications (e.g. severe myopia and thin conjunctiva) following implantation of the device; patients diagnosed with Angle Closure Glaucoma.

**WARNINGS.** Rx only: This device is restricted to sale by, or on the order of, a physician. For one-time use only. Do not reuse or re-sterilise. Reuse, or re-sterilisation may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in serious patient injury, illness, blindness, or death. Reuse, or re-sterilisation may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, blindness, or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy. Long-term effects of Mitomycin C (MMC) with the use of this device have not been evaluated. Necessary precautions and interventions on the use of MMC are highly recommended. Viscoelastics have not been tested with this device. However, in an emergency when all other therapies have failed, the use of hydroxylmethyl-cellulose (HPMC) may be an option. Use of HPMC should be a last resort to correct a flat chamber with the PRESERFLO™ MicroShunt and may risk loss of flow through the device for one or more weeks after use necessitating close or more frequent observation of IOP. **POTENTIAL COMPLICATIONS / ADVERSE EVENTS.** The complications during and after surgery may include: Glaucoma progression not controlled, difficulty in inserting the PFMS, extended surgical procedure, tube migration out of anterior chamber, flat anterior chamber, shallow anterior chamber, excessive bleeding in anterior chamber or eye, PFMS touches cornea or iris, intraocular pressure too high or low, viscoelastic used in anterior chamber, choroidal effusion or hemorrhage, retinal detachment, proliferative retinopathy, hyphema, hypotony or hypotony maculopathy, phthisis bulbi, endophthalmitis, tube erosion through conjunctiva, tube block by iris or vitreous or fibrin, uveitis, diplopia, aqueous misdirection, corneal complications (abrasion, edema, ulceration, infection, decompensation, bullous keratopathy, endothelial cell loss, Descemet striae), partial or complete vision loss, globe perforation, bleb leak, blebitis, cystic bleb, bleb failure, pupillary block, ptosis, macular edema, prolonged inflammation, use of glaucoma medications, pain, conjunctival complications (dehiscence, dissection, hemorrhage, hyperemia, scar, ulcer), iris adhesions/ synechiae, cataract development or progression, explantation of the PFMS, encapsulation reaction, fibrin in anterior chamber, visual field damage, headache, vitreous hemorrhage, and suture related complications.

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