COMMAND IOP WITHOUT COMPROMISE

Introducing **PRESERFLO[™] MicroShunt**. The controlled, *ab externo* filtration device that delivers a unique combination of efficacy and safety for patients with POAG.¹

Engineered to control IOP while decreasing post-operative risk^{1,2}

3 mm distal tail enables formation of posterior bleb¹⁻³



1 mm fin prevents migration and periannular leakage^{1,2}



Beveled tip visually aids in correct device orientation¹



8.5 mm length and 70 µm lumen optimise aqueous flow and decrease hypotony risk¹⁻³

Order Information		
ORDER NUMBER	CONTACT	WEBSITE
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References:

Baker D, Barnebey 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
Pinchuk L, Riss I, Batlle JF, et al. The development of a micro-shunt made from poly(styrene-*block*-isobutylene-*block*-styrene) to treat glaucoma. *J Biomed Mater Res* Part B. 2017;105B:211-221. DOI:10.1002/jbm.b.33525.
Sadruddin O, Pinchuk L, Angeles R, Palmberg P. Ab externo implantation of the MicroShunt, a poly (styrene-block-isobutylene-block-styrene) surgical device for the treatment of primary open-angle glaucoma: a review. *Eye Vis (Lond)*. 2019;6:36.

IMPORTANT SAFETY INFORMATION

INDICATION FOR USE. The PRESERFLOTM 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 PRESERFLOTM 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; Preexisting 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 PRESERFLOTM 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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