

# Patient Information Brochure

**Name of medical device:** PRESERFLO™  
MicroShunt & 3mm Scleral Marker.

**Intended purpose:** The PRESERFLO™ MicroShunt & 3mm Scleral Marker 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.

**Special operating instructions for the use of the device:** The device is designed to be implanted under the subconjunctival/Tenon space. Surgeons should be well familiarized with the device with proper training. Make sure to check the expiration date.

**Intended performance of the device:** This device is designed to be implanted to reduce pressure in the eye.

**Undesirable side effects that could be caused by use of the device:** Glaucoma progression not controlled, 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 device, encapsulation reaction, fibrin in anterior chamber, visual field damage, globe perforation, headache, vitreous hemorrhage, and suture related complications.

**Warnings and Precautions:** The device is for one-time use only. Do not reuse or re-sterilize. Reuse or re-sterilization 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-sterilization 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.

There is no risk of magnetic field interference, and this device is magnetic resonance safe.

**What may happen after surgery:** You may need to visit the doctor frequently to monitor the intraocular pressure and to determine if the tube is open.

If you are experiencing any of the undesirable side effects mentioned above, please consult your doctor immediately.

For any questions or concerns, contact Glaukos Inc. In case of any serious incident please report to Glaukos via [medicalsafety@glaukos.com](mailto:medicalsafety@glaukos.com) and the Therapeutic Goods Administration using the following link: [www.tga.gov.au/reporting-adverse-events](http://www.tga.gov.au/reporting-adverse-events)

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DWG-INF-0385-00R01



**MD** PRESERFLO™ MicroShunt

**Model: GLT-001**



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**THIS PAGE IS NOT PART OF THE PATIENT INFORMATION BROCHURE**

<b>Title:</b>	Patient Information Brochure - DWG-INF-0385-00
<b>Doc. #</b>	MD-SPEC-00647 (v1.0)
<b>Description:</b>	Folded 8.5" x 11" sheet
<b>Prepress:</b>	Print Ready Digital file provided by InnFocus, proof provided by Docunet.
<b>Finished Size:</b>	4.25" width x 11" height
<b>Bindery:</b>	Half Fold on 11" height
<b>Font:</b>	Arial
<b>Preferred Vendor:</b>	Docunet Corp.  2435 Xenium Lane North Plymouth, MN 55441 <a href="http://www.docunetworks.com">www.docunetworks.com</a> Tel: (763) 475-9600
<b>PN / Rev.</b>	DWG-INF-0385-00R01

<b>Specification and Inspection Notes Table:</b>		
<b>Specification</b>		<b>Inspection Method</b>
<b>1</b>	<b>Packaging</b>	
A	Shipper box (First Package) free from visual damage (holes, tears, wet spots, etc.)	Visual Inspection (unaided eye)
<b>2</b>	<b>Identification and Traceability</b>	
A	Packing list indicating (at a minimum) the PO #, InnFocus P/N and revision and/or manufacturer P/N, description, and quantity.	Visual Inspection (unaided eye)
B	Bulk and Assembly Packing will be labeled with (at a minimum) InnFocus P/N and revision and/or manufacturer P/N, Lot Number, Description and Quantity in each package.	
<b>3</b>	<b>Material Specification(s)</b>	
A	Part: Patient Information Brochure	Confirm Certificate of Compliance is present, and specifications met
B	Paper Stock: 40# Opaque white	
<b>4</b>	<b>Physical / Functional Specifications</b>	
A	Component must be clean from ink stains, marks, dirt, oils, and other contaminants.	Visual Inspection (unaided eye)
B	Secondary package must be intact, sealed, and free from obvious damage (ie: leaks, breaks, or broken seals).	
C	Inspect Physical Patient Information Brochure Artwork against DWG-INF-0385-00	
D	Text Print: Black Throughout	