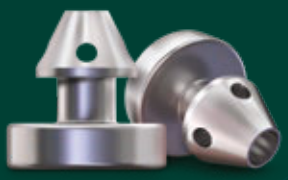
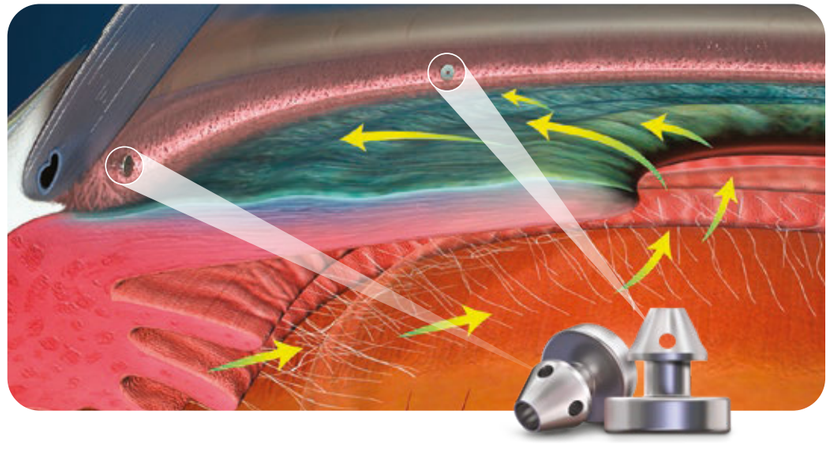
GLAUKOS®

iStent inject® W



EVOLVING DESIGN.
ADVANCING PREDICTABILITY.

TWO INJECTABLE STENTS. ONE INCREDIBLE GAME-CHANGER.



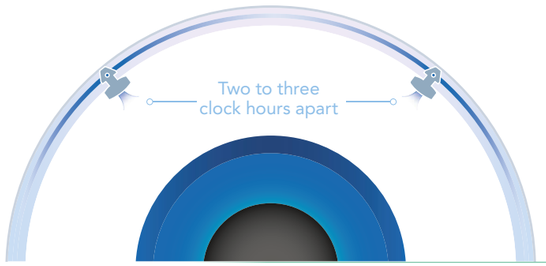
With two stents preloaded in a single-use injector, iStent *inject* W represents the next generation of trabecular micro-bypass technology for patients with glaucoma, and is designed to:

- Optimize natural outflow
- Significantly reduce IOP
- Provide the predictability and precision to meet the needs of your practice
- Prioritize patient safety

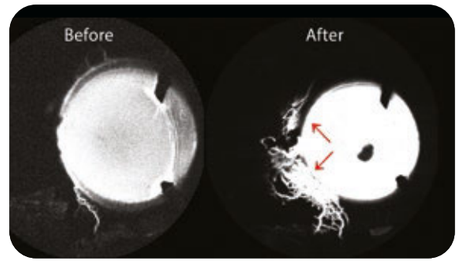
Start by Restoring the Natural Outflow Pathway

iStent *inject* W creates two patent bypass pathways through the trabecular meshwork – the main source of resistance for aqueous outflow – resulting in multi-directional flow through Schlemm's canal. And it is one of the smallest medical devices known to be implanted in the human body. Together, these unique advantages are designed to provide exceptional results in a truly micro-invasive approach.

iStent *inject* W placement in the inferonasal quadrant



Aqueous angiography study conducted by Alex Huang, MD[1]



With iStent inject *W, two multi-directional stents are placed two to three clock hours apart. Together, they are designed to deliver access to multiple collector channels and arcs of flow that can span five to six clock hours. iStent* inject *W may also* ***re-establish flow in previously dormant outflow channels****.*[2]

Prioritize Safety and Outcomes

Putting the primary emphasis on maximizing benefits and minimizing long-term complications, iStent *inject* W is designed to support optimal outcomes after cataract surgery, and much more.

- Micro-invasive and astigmatically-neutral
- Utilizes the conventional outflow pathway
- Leaves natural anatomy intact, preserving the potential for future treatment options, including drug delivery devices
- Minimally traumatic to delicate eye tissue and spares conjunctival tissue
- Reduces the risk of hypotony by utilizing the natural episcleral venous pressure
- Offers postoperative care profile similar to cataract surgery

iStent *inject* US IDE Trial[3]

Lowest reported rates of significant endothelial cell loss (ECL ≥30%) and peripheral anterior synechiae (PAS) of any trabecular bypass MIGS pivotal trial. No reports of hypotony, significant hyphema, or choroidal hemorrhage or effusion.

MICRO STENTS. MACRO EFFICACY.

iStent *inject* W builds on the trabecular micro-bypass technology of iStent *inject*, which has demonstrated efficacy across a wide range of clinical studies.

iStent *inject* US Pivotal Trial[3]

In the US IDE Trial (n=505 subjects), iStent *inject* met the study endpoints and demonstrated a clinically significant reduction in IOP for iStent *inject* subjects at 24 months.

Proven Efficacy, Meaningful Results:

- 75.8% of iStent *inject* subjects had ≥ 20% reduction in unmedicated DIOP at 24 months
- 7.0 mmHg reduction from baseline in unmedicated DIOP at 24 months

Other Observed Data:

- 17.1 mmHg mean medication-free IOP at 24 months – **the lowest reported post-op mean IOP of any trabecular bypass stent***
- 63.2% medication-free DIOP ≤ 18 mmHg at 24 months
- Mean of 0.4 medications at 23 months, down from preoperative mean of 1.6 for the treatment arm

Medication reduction is subject to the discretion of the physician.

*In any trabecular bypass MIGS pivotal trial.

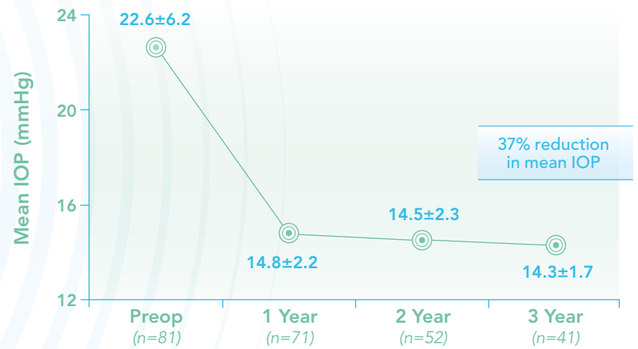
Independent Clinical Study Results

Additional independent, long-term studies of Glaukos trabecular micro-bypass technology suggest that results are maintained several years after the procedure.

Study	# of Subjects (at endpoint)	Post-op Mean IOP (mmHg)	% IOP Reduction	% Medication Reduction
Guedes[4] (12M)	23	13.1	19.1%	94.1%
Clement[5] (12M)	165	14.0	23.2%	71.5%
Manning[6] (12M)	70	14.4	29.4%	94.7%
Hengerer[7] (36M)	41	14.3	37.0%	68.0%
Arriola-Villalobos[8] (48M)	20	16.25	36.92%	42.3%

Long-term IOP and Medication Reduction

Intraocular Pressure Over Time[7]



In a consecutive case series with three-year follow-up, mean IOP was 14.3 ± 1.7 mmHg, representing a 37% reduction from preoperative medicated mean IOP; and 100% of eyes had IOP ≤ 18 mmHg.

Mean medication use was decreased from 2.5 to 0.8 medications at three years, a 68% reduction; and 74% of eyes were using 0 or 1 medication compared to 21% preoperatively.

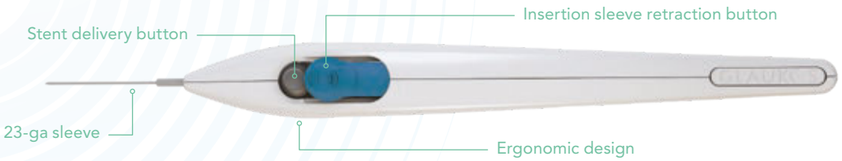
EXCEPTIONAL ELEGANCE. ADVANCED INNOVATION.

The iStent *inject* W System is engineered to provide an enhanced surgical experience and ensure confident delivery, for every procedure. With next-generation stent design, featuring a wide flange at its base, iStent *inject* W is designed to optimize stent visualization and placement, deliver procedural predictability, and increase peace of mind.

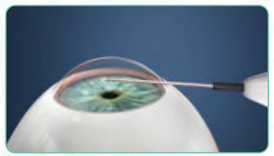
iStent *inject* W System

iStent *inject* W stents are made of titanium and coated with heparin

Insertion tube with window optimizes visualization

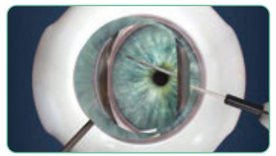


iStent *inject* W Procedure Overview

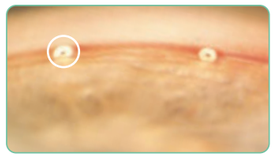


Introduce the iStent *inject* W inserter into the eye through the cataract incision.

Place the trocar through the center of the trabecular meshwork and into the back wall of Schlemm's canal. Deploy the first stent.



Remaining in the chamber, maneuver the inserter two to three clock hours away. Deploy the second stent.



Two properly placed stents optimize outflow.

OUR COMPREHENSIVE SUPPORT. YOUR UNCOMPROMISING PATIENT CARE.

Glaukos Provides Extensive Tools, Resources, and Support

Integrating iStent *inject* W into your practice helps you expand care, and provide a wider range of benefits to many of your patients. As a trusted industry leader—and the corporate founder of MIGS—we have the experience, tools, and training to make integration easy. We lead the industry in clinical support and patient education resources, including:

- Highly-personalized practice resources
- In-depth training, including online modules and hands-on wet labs
- Robust tools to help you educate patients and staff
- Unrivaled reimbursement support

You're Already Seeing Potential iStent *inject* W Patients

iStent *inject* W is indicated for use in adult patients with mild-to-moderate open-angle glaucoma that are undergoing cataract surgery. A review of Medicare claims data shows that approximately one in five cataract patients are also potential candidates for iStent *inject* W. By taking advantage of this one-time opportunity, you may be able to provide your patients with better IOP control and a reduced dependence on medication.

iStent *inject*® W

TWO OUTFLOW PATHWAYS. ONE NEW STANDARD.

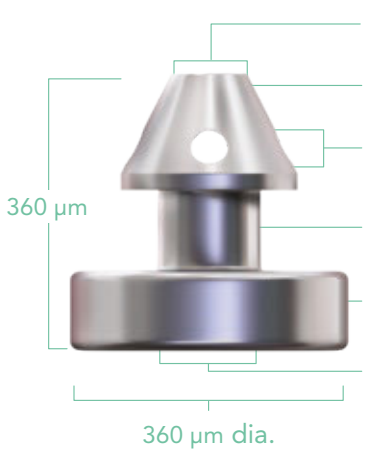
iStent *inject* W is built on a solid, dependable foundation of proven efficacy and safety in thousands of eyes worldwide.

Optimized Outflow: Two multi-directional stents designed to restore natural outflow.

Clinically Proven: Significant IOP reduction across a wide range of clinical studies.

Procedural Elegance: Predictability and precision to meet the needs of your practice.

Proven Safety: Safety profile similar to cataract surgery alone.



Central Outlet
80 µm dia.

Head
Resides in Schlemm's canal

Side Flow Outlets (4)
50 µm dia.

Thorax
Held by the trabecular meshwork

Wide Flange
Resides in the anterior chamber

Central Inlet
80 µm dia.

Ordering Information

- Order Number: G2W-US
- 800-GLAUKOS (452-8567)
- CustomerService@glaukos.com
- glaukos.com

REFERENCES: 1. Huang AS, Penteado RC, Papoyan V, Voskanyan L, Weinreb RN. Aqueous angiographic outflow improvement after trabecular microbypass in glaucoma patients. *Ophthalmology Glaucoma.* 2019, doi: https://doi.org/10.1016/j.ogla.2018.11.010. **2.** Data on file, Glaukos Corporation. **3.** Samuelson TW, Sarkisian SR, Lubeck DM, et al. Prospective, randomized, controlled pivotal trial of an ab interno implanted trabecular micro-bypass in primary open-angle glaucoma and cataract. *Ophthalmology.* Jun 2019;126(6):811-821. **4.** Guedes RAP, Gravina DM, Lake JC, Guedes VMP, Chaoubah A. Intermediate results of iStent or iStent *inject* implantation combined with cataract surgery in a real-world setting: a longitudinal retrospective study. *Ophthalmol Ther.* March 2019;8(1):87-100. **5.** Clement CI, Howes F, Ioannidis AS, Shiu M, Manning D. One-year outcomes following implantation of second-generation trabecular micro-bypass stents in conjunction with cataract surgery for various types of glaucoma or ocular hypertension: multicenter, multi-surgeon study. *Clin Ophthalmol.* 2019:13;491-499. **6.** Manning D. Real-world case series of iStent or iStent *inject* trabecular micro-bypass stents combined with cataract surgery. *Ophthalmology & Therapy.* 2019. doi:https://doi.org/10.1007/s40123-019-00208-x. **7.** Hengerer FH, Auffarth GU, Riffel C, Conrad-Hengerer I. Prospective, non-randomized, 36-month study of second-generation trabecular micro-bypass stents with phacoemulsification in eyes with various types of glaucoma. *Ophthalmol Ther.* 2018 Dec;7(2):405-415. **8.** Arriola-Villalobos P, Martinez-de-la-Casa JM, Diaz-Valle D, et al. Glaukos iStent *inject* trabecular micro-bypass implantation associated with cataract surgery in patients with coexisting cataract and open-angle glaucoma or ocular hypertension: a long-term study. *J Ophthalmology.* 2016;1-7.

INDICATION FOR USE. The iStent *inject*® W Trabecular Micro-Bypass System Model G2-W is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma. **CONTRAINDICATIONS**. The iStent *inject* W is contraindicated in eyes with angle-closure glaucoma, traumatic, malignant, uveitic, or neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retrobulbar tumor, thyroid eye disease, or Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. **WARNINGS.** Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. **MRI INFORMATION.** The iStent *inject* W is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details. **PRECAUTIONS.** The surgeon should monitor the patient postoperatively for proper maintenance of IOP. The safety and effectiveness of the iStent *inject* W have not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, abnormal anterior segment, chronic inflammation, prior glaucoma surgery (except SLT performed > 90 days preoperative), glaucoma associated with vascular disorders, pseudoexfoliative, pigmentary or other secondary open-angle glaucomas, pseudophakic eyes, phakic eyes without concomitant cataract surgery or with complicated cataract surgery, eyes with medicated IOP > 24 mmHg or unmedicated IOP < 21 mmHg or > 36 mmHg, or for implantation of more or less than two stents. **ADVERSE EVENTS.** Common postoperative adverse events reported in the iStent *inject*® randomized pivotal trial included stent obstruction (6.2%), intraocular inflammation (5.7% for iStent *inject* vs. 4.2% for cataract surgery only), secondary surgical intervention (5.4% vs. 5.0%) and BCVA loss ≥ 2 lines ≥ 3 months (2.6% vs. 4.2%). **CAUTION:** Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.

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