INTRODUCING

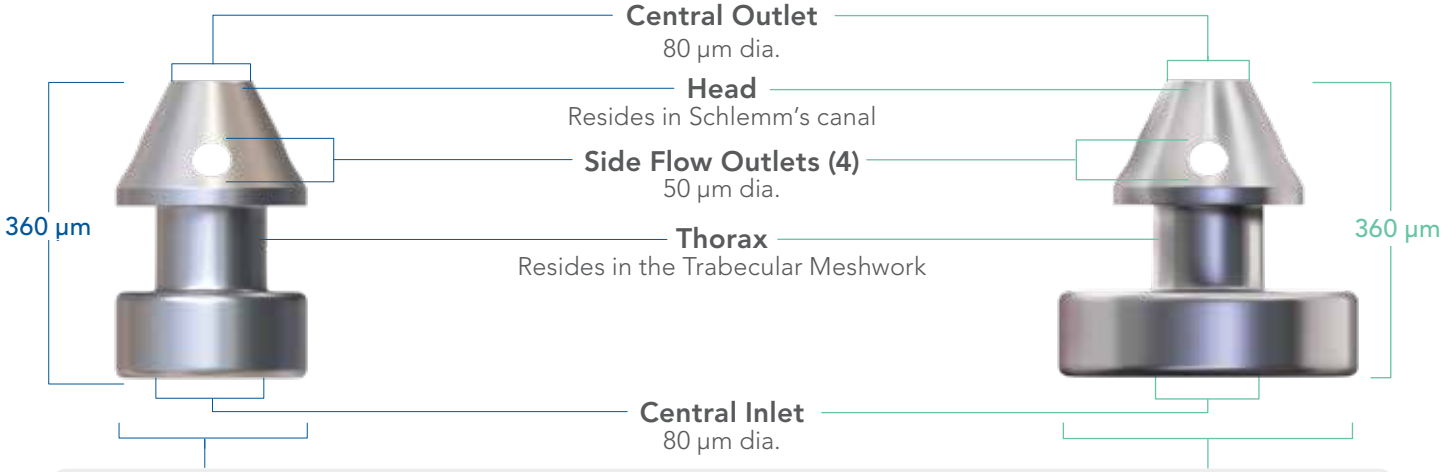
iStent *inject*® W

Featuring a wide flange at its base, the new precision-engineered iStent *inject*® W is designed to optimize stent visualization and placement, enhance procedural predictability, and increase peace of mind.

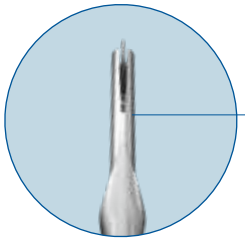
iStent *inject*®

iStent *inject*® W

Stent Specifications

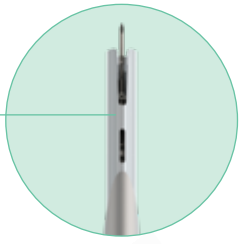


Injector System



Single v-slot window

Shorter window with bridge optimizes visualization of both stents



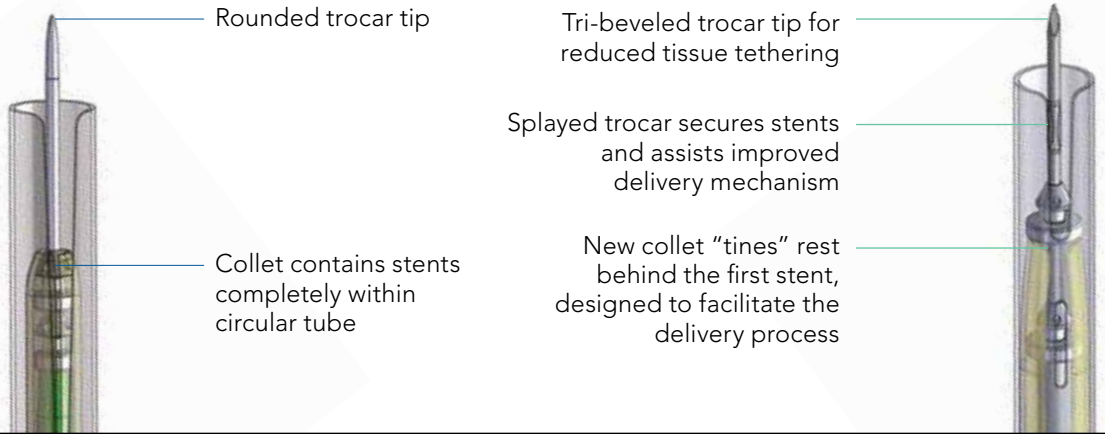
Rounded trocar tip

Tri-beveled trocar tip for reduced tissue tethering

Splayed trocar secures stents and assists improved delivery mechanism

New collet "tines" rest behind the first stent, designed to facilitate the delivery process

Collet contains stents completely within circular tube



iStent *inject*® W

EVOLVING DESIGN. ADVANCING PREDICTABILITY.

Its advantages are easy to see.

A WIDE FLANGE at the base of iStent *inject* W is designed to:

- Enhance visibility
- Facilitate seamless implantation
- Provide observable positioning confirmation
- Deliver procedural consistency and predictability

Built on a proven platform.

Representing the next generation of Glaukos trabecular micro-bypass technology, 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[1,2]
- **Procedural Elegance:** Predictability and precision to meet the needs of your practice
- **Proven Safety:** Safety profile similar to cataract surgery alone[1]

All with the exceptional customer support you've come to expect from Glaukos.

GLAUKOS CORPORATION
229 Avenida Fabricante • San Clemente, CA • 92672 • USA
tel 800.GLAUKOS (452.8567) • fax 949.362.9838 • Glaukos.com

GLAUKOS®

INDICATION FOR USE. The iStent *inject*® W is intended to reduce intraocular pressure safely and effectively in patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma. The iStent *inject*® W can deliver two (2) stents on a single pass, through a single incision. The implant is designed to stent open a passage through the trabecular meshwork to allow for an increase in the facility of outflow and a subsequent reduction in intraocular pressure. The device is safe and effective when implanted in combination with cataract surgery in those subjects who require intraocular pressure reduction and / or would benefit from glaucoma medication reduction. The device may also be implanted in patients who continue to have elevated intraocular pressure despite prior treatment with glaucoma medications and conventional glaucoma surgery.

REFERENCES: 1. iStent inject® Trabecular Micro-Bypass System: Directions for Use, Part # 45-0176. **2.** 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.

iStent *inject*® W

POWERFUL. PREDICTABLE. PROVEN

PROVEN PLATFORM

iStent *inject*® is the gold standard in Trabecular Micro-Bypass surgery, continuing the legacy of excellence set throughout 20 years of iStent® devices. It's backed by the most robust, diverse, and longest-term body of clinical evidence for any MIGS procedure available today, given through clinical rigor and integrity.

8 year study with iStent **demonstrated sustained protection against visual field loss,** as well as preservation of best corrected visual acuity, cup to disc ratio, and retinal nerve fiber layer thickness[9]

8

38

38 publications **demonstrate the power of iStent technologies** to **protect against visual field loss**†

PROTECTS VISUAL FIELDS[1,9]

<0.01 decibel mean change in visual field mean deviation from baseline at 24 months in iStent *inject*-treated eyes in a pivotal trial[1]

<0.01

PROVEN

LOW RATE OF SECONDARY SURGERY INTERVENTIONS[4,5,10]

2.6% of 778 patients in a **meta-analysis** of stand alone iStent *inject* eyes went on to require secondary incisional surgery during follow up[5]

2.6%

4% of 125 patients in **real world study** of stand alone and combined iStent *inject* cases required a secondary procedure during **5 years of follow up**[4]

4%

1%

Only 1% of 186 eyes in a **randomised controlled trial** went on to require secondary incisional surgery during **3 years follow up**[10]

LEGACY OF EXCELLENCE

20 Years of Data. 20K+ Eyes Studied. 20+ Countries.

Scientific evidence and clinical rigor have been at the heart of Glaukos, with the earliest publication on iStent® dating back to 2002 - years prior to the iStent® pivotal trial. Today, this same rigor and integrity is applied to our business as we remain focused on generating strong clinical evidence.

iSTENT TECHNOLOGIES
MORE THAN
ONE MILLION
iSTENT DEVICES
IMPLANTED WORLDWIDE

1. Samuelson, Thomas W., et al. "Prospective, randomized, controlled pivotal trial of an ab interno implanted trabecular micro-bypass in primary open-angle glaucoma and cataract: two-year results." Ophthalmology 126.6 (2019): 811-821. **2.** Lindstrom, Richard, et al. "Four-year outcomes of two second-generation trabecular micro-bypass stents in patients with open-angle glaucoma on one medication." Clinical Ophthalmology (Auckland, NZ) 14 (2020): 71. **3.** Berdahl, John, et al. "iStent inject trabecular micro-bypass stents with topical prostaglandin as standalone treatment for open-angle glaucoma: 4-year outcomes." Clinical & Experimental Ophthalmology 48.6 (2020): 767-774. **4.** Hengerer, Fritz H., Gerd U. Auffarth, and Ina Conrad-Hengerer. "iStent inject Trabecular Micro-Bypass with or Without Cataract Surgery Yields Sustained 5-Year Glaucoma Control." Advances in Therapy (2022): 1-15. **5.** Healey, Paul R., et al. "Standalone iStent trabecular micro-bypass glaucoma surgery: A systematic review and meta-analysis." Journal of Glaucoma 30.7 (2021): 606-620. **6.** Berdahl, J., Voskanyan, L., Myers, J. S., Katz, L. J., & Samuelson, T. W. (2020). iStent inject trabecular micro-bypass stents with topical prostaglandin as standalone treatment for open-angle glaucoma: 4-year outcomes. Clinical & Experimental Ophthalmology, 48(6), 767-774. **7.** Ferguson, Tanner J., et al. "iStent trabecular microbypass stent implantation with phacoemulsification in patients with open-angle glaucoma: 6-year outcomes." Clinical Ophthalmology (Auckland, NZ) 14 (2020): 1859. **8.** Ziaei, Hadi, and Leon Au. "Manchester iStent study: long-term 7-year outcomes." Eye 35.8 (2021): 2277-2282. **9.** Salimi, Ali, Harrison Watt, and Paul Harasymowycz. "Long-term outcomes of two first-generation trabecular micro-bypass stents (iStent) with phacoemulsification in primary open-angle glaucoma: eight-year results." Eye and Vision 8.1 (2021): 1-12. *Consistent cohort. **10.** Samuelson TW, on behalf of the iStent inject Pivotal Trial Study Team. Three-Year Effectiveness and Safety of 2nd-Generation Trabecular Micro-Bypass (iStent inject). Paper at the Annual Meeting of the American Academy of Ophthalmology (AAO). Virtual Meeting: November 13-15, 2020. † Data on file.

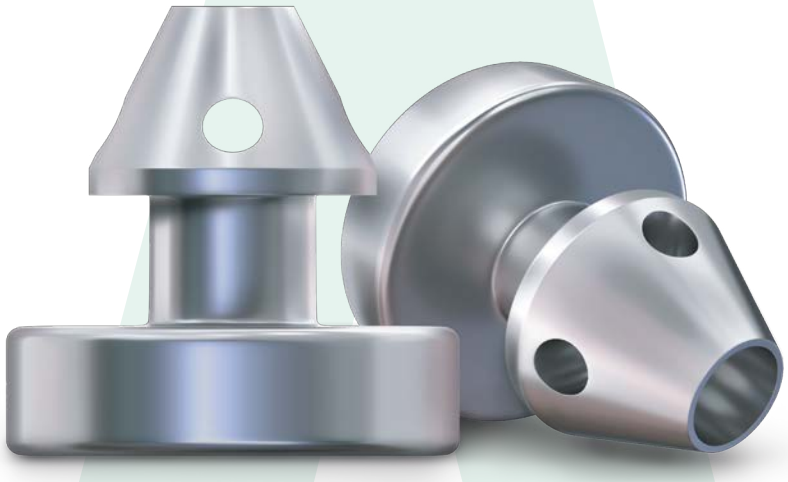
iStent *inject*® W IMPORTANT SAFETY INFORMATION

INDICATION FOR USE: The iStent *inject* W, is intended to reduce intraocular pressure safely and effectively in patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma. The iStent *inject* W, can deliver two (2) stents on a single pass, through a single incision. The implant is designed to stent open a passage through the trabecular meshwork to allow for an increase in the facility of outflow and a subsequent reduction in intraocular pressure. The device is safe and effective when implanted in combination with cataract surgery in those subjects who require intraocular pressure reduction and/or would benefit from glaucoma medication reduction. The device may also be implanted in patients who continue to have elevated intraocular pressure despite prior treatment with glaucoma medications and conventional glaucoma surgery. **CONTRAINDICATIONS:** The iStent *inject* W System is contraindicated under the following circumstances or conditions: • In eyes with primary angle closure glaucoma, or secondary angle-closure glaucoma, including neovascular glaucoma, because the device would not be expected to work in such situations. • In patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. **WARNINGS/ PRECAUTIONS:** • For prescription use only. • This device has not been studied in patients with uveitic glaucoma. • Do not use the device if the Tyvek® lid has been opened or the packaging appears damaged. In such cases, the sterility of the device may be compromised. • Due to the sharpness of certain injector components (i.e. the insertion sleeve and trocar), care should be exercised to grasp the injector body. Dispose of device in a sharps container. • iStent *inject* W is MR-Conditional; see MRI Information below. • Physician training is required prior to use of the iStent *inject* W System. • Do not re-use the stent(s) or injector, as this may result in infection and/or intraocular inflammation, as well as occurrence of potential postoperative adverse events as shown below under "Potential Complications." • There are no known compatibility issues with the iStent *inject* W and other intraoperative devices. (e.g., viscoelastics) or glaucoma medications. • Unused product & packaging may be disposed of in accordance with facility procedures. Implanted medical devices and contaminated products must be disposed of as medical waste. • The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. If intraocular pressure is not adequately maintained after surgery, the surgeon should consider an appropriate treatment regimen to reduce intraocular pressure. • Patients should be informed that placement of the stents, without concomitant cataract surgery in phakic patients, can enhance the formation or progression of cataract. **ADVERSE EVENTS:** Please refer to Directions For Use for additional adverse event information. **CAUTION:** Please reference the Directions For Use labelling for a complete list of contraindications, warnings and adverse events.

TMB® TRABECULAR MICRO-BYPASS

GLAUKOS TRANSFORMING VISION

iStent inject® W



POWERFUL
PREDICTABLE
PROVEN

THE #1 MIGS DEVICE WORLDWIDE*

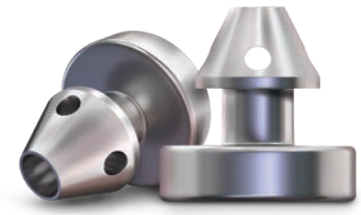
Powerful technology for sustained intraocular pressure and medication reduction. **Predictable outcomes** from a truly tissue-sparing procedure. All on a **proven platform** with the most clinical evidence of any MIGS device.

Experience the latest evolution of the iStent® legacy of excellence in your practice.

*Based on units sold.

TMB® TRABECULAR MICRO-BYPASS

GLAUKOS® TRANSFORMING VISION



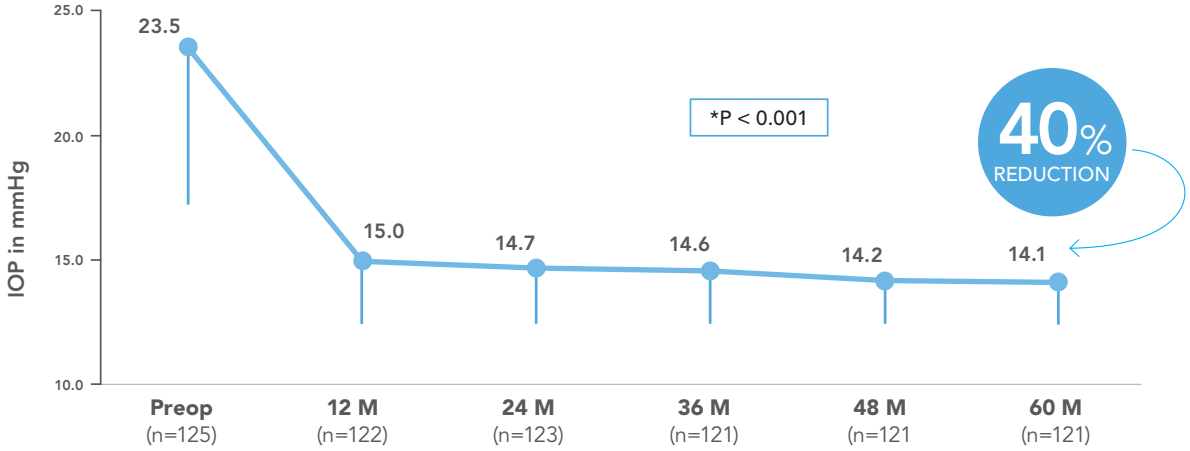
iStent *inject*® W

POWERFUL. PREDICTABLE. PROVEN

POWERFUL TECHNOLOGY

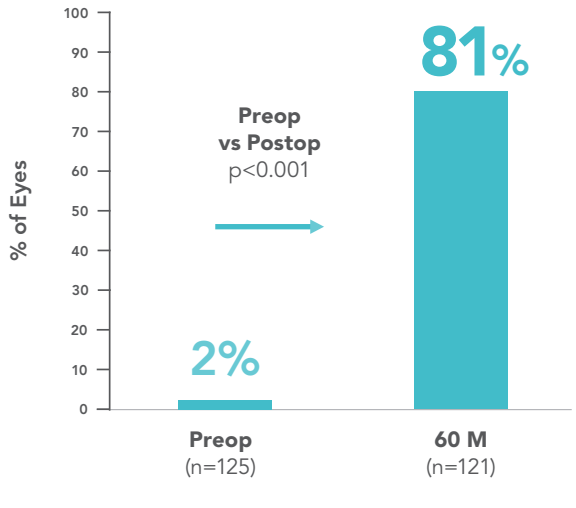
iStent *inject*® has the lowest reported post-op mean intraocular pressure (IOP) of any trabecular bypass stent in a pivotal trial at 24 months[1] and has consistently demonstrated IOP reductions in excess of 30% vs baseline through long term, independent, real world studies[2-5].

5 YEAR CLINICAL OUTCOMES[4]



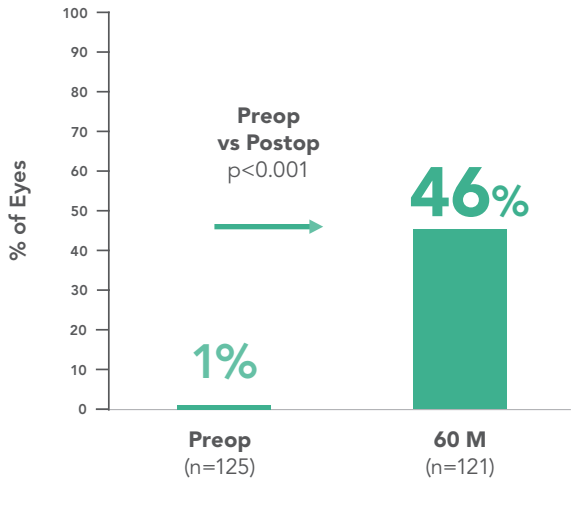
M = months; Preop = preoperative; IOP = intraocular pressure
Vertical bars represent standard deviation

% OF PATIENTS BELOW 15mmHg[4]



IOP ≤15 mmHg

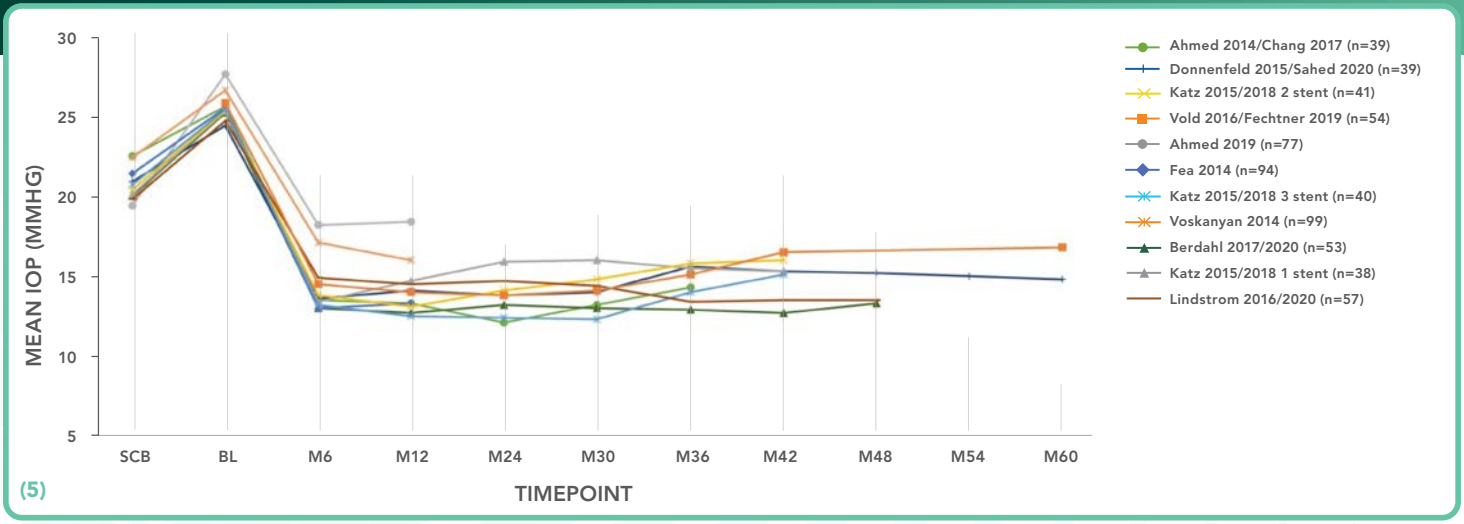
% OF PATIENTS MEDICATION FREE[4]



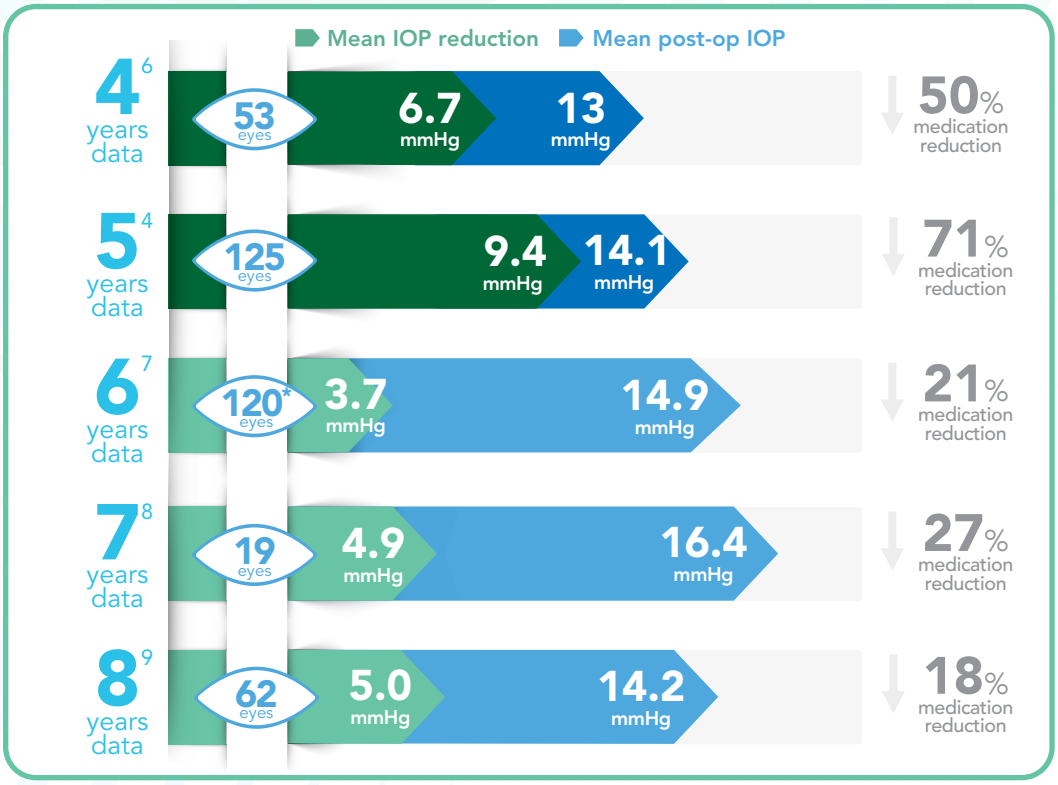
Medication-Free

PREDICTABLE OUTCOMES

Year after year, study after study, iStent *inject*® has produced consistent and predictable results. Featuring a wide flange at its base, the new precision-engineered iStent *inject*® W is designed to optimize stent visualization and placement, enhance procedural predictability, and increase peace of mind.



(5)



Multiple independent real-world studies demonstrate the long-term outcomes of iStent® technologies - most of any MIGS procedure today

16

studies with 4-8 years follow up

Amico Yasna Pars (Pr.J.S.Co)

Tel: +9821-71137000
Fax: +9821-71137300
2nd Floor, No. 1698, Shariati Ave., Tehran, Iran Postal Code:1914744755
www.aypmedical.com info@aypmedical.com