



# Study Published in Journal of Glaucoma Evaluates a Single Glaukos iStent® Trabecular Micro-Bypass Stent as a Standalone Procedure

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*Case Series of 42 Pseudophakic Eyes Shows Mean Medicated Intraocular Pressure Decrease of 6.64 mm Hg in 21 Eyes Followed Two Years Postoperatively*

SAN CLEMENTE, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures designed to transform the treatment of glaucoma, today announced that a study published recently in the [Journal of Glaucoma](#) showed that a single *iStent® Trabecular Micro-Bypass Stent* significantly reduced intraocular pressure (IOP) when implanted as a standalone procedure in pseudophakic eyes with open-angle glaucoma. Pseudophakic refers to eyes in which the natural lens has previously been removed and replaced with an intraocular lens.

In this retrospective, consecutive case series, researchers from the University of South Dakota Sanford School of Medicine and Sioux Falls-based Vance Thomson Vision evaluated *iStent* procedure outcomes in 42 pseudophakic eyes with preoperative mean IOP of 20.26 mm Hg. In 21 eyes followed for two years, mean medicated IOP decreased 6.64 mm Hg to 13.62 mm Hg, or 33%.

In total, 96% of study patients with preoperative medicated IOP  $\geq$  19 mm Hg achieved an IOP reduction at their last collected follow-up. With a low rate of postoperative IOP spikes and only one patient requiring additional glaucoma surgery, the safety profile was favorable. In order to mimic the device's actual clinical use, study researchers enrolled patients with primary open-angle glaucoma, normal tension glaucoma and ocular hypertension, with no other exclusion criteria.

"While multiple studies and years of real-world experience have demonstrated the ability of *iStent* to achieve sustained IOP reductions when used in combination with cataract surgery, we wanted to explore the IOP-lowering performance of *iStent* as a sole procedure in pseudophakic eyes," said John P. Berdahl, MD, who performed all of the procedures evaluated in the study. "In this series of *iStent* procedures occurring between October 2012 and May 2015, we recorded IOP reductions at one and two years postoperatively that were both clinically and statistically significant."

Dr. Berdahl added, "These types of results are important to glaucoma surgeons and patients because landmark studies such as the Early Manifest Glaucoma Trial have shown that every 1 mm Hg improvement in IOP can reduce the likelihood of disease progression."

The *iStent* was approved by the U.S. Food & Drug Administration (FDA) in June 2012 and is indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication. Made of surgical-grade non-ferromagnetic titanium that is coated with heparin, the *iStent* is approximately 1.0 mm long and 0.33 mm wide. Glaukos believes it is the smallest medical device ever approved by the FDA.

Glaucoma is characterized by progressive, irreversible and largely asymptomatic vision loss caused by optic nerve damage. There is no cure for the disease and reducing IOP is the only proven treatment. According to Market Scope, more than 80 million people worldwide have glaucoma, including 4.5 million people in the United States. Open-angle glaucoma is the most common form, affecting approximately 3.6 million people in the United States.

### **About *iStent Trabecular Micro-Bypass Stent (U.S.)***

**Indication for Use:** The *iStent Trabecular Micro-Bypass Stent* is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication.

**Contraindications:** The *iStent* is contraindicated in eyes with primary or secondary angle closure glaucoma, including neovascular glaucoma, as well as 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:** Gonioscopy should be performed prior to surgery to exclude PAS, rubeosis, and other angle abnormalities or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. The *iStent* is MR-Conditional meaning that the device is safe for use in a specified MR environment under specified conditions, please see label for details.

**Precautions:** The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The safety and effectiveness of the *iStent* has not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, chronic inflammation, or an abnormal anterior segment, in pseudophakic patients with glaucoma, in patients with pseudoexfoliative glaucoma, pigmentary, and uveitic glaucoma, in patients with unmedicated IOP less than 22 mmHg or greater than 36 mmHg after “washout” of medications, or in patients with prior glaucoma surgery of any type including argon laser trabeculoplasty, for implantation of more than a single stent, after complications during cataract surgery, and when implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract.

**Adverse Events:** The most common post-operative adverse events reported in the randomized pivotal trial included early post-operative corneal edema (8%), BCVA loss of  $\geq 1$  line at or after the 3 month visit (7%), posterior capsular opacification (6%), stent obstruction (4%) early post-operative anterior chamber cells (3%), and early post-operative corneal abrasion (3%). Please refer to Directions for Use for additional adverse event information.

**Caution:** Federal law restricts this device to sale by, or on the order of, a physician. Please reference the Directions for Use labeling for a complete list of contraindications, warnings, precautions, and adverse events.

## About Glaukos

Glaukos ([www.glaukos.com](http://www.glaukos.com)) is an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures designed to transform the treatment of glaucoma, one of the world's leading causes of blindness. The company pioneered Micro-Invasive Glaucoma Surgery, or MIGS, to revolutionize the traditional glaucoma treatment and management paradigm. Glaukos launched the *iStent*<sup>®</sup>, its first MIGS device, in the United States in July 2012 and is leveraging its platform technology to build a comprehensive and proprietary portfolio of micro-scale injectable therapies designed to address the complete range of glaucoma disease states and progression. The company believes the *iStent*, measuring 1.0 mm long and 0.33 mm wide, is the smallest medical device ever approved by the FDA.

## Forward-Looking Statements

All statements other than statements of historical facts included in this press release that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. Although we believe that we have a reasonable basis for forward-looking statements contained herein, we caution you that they are based on current expectations about future events affecting us and are subject to risks, uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control, that may cause our actual results to differ materially from those expressed or implied by forward-looking statements in this press release. These potential risks and uncertainties include, without limitations, the continued efficacy of our products as might be suggested in the study described herein. These risks, uncertainties and factors are described in detail under the caption "Risk Factors" and elsewhere in our filings with the Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 filed with the Securities and Exchange Commission. Our filings with the Securities and Exchange Commission are available in the Investor Section of our website at [www.glaukos.com](http://www.glaukos.com) or at [www.sec.gov](http://www.sec.gov). In addition, information about the risks and benefits of our products is available on our website at [www.glaukos.com](http://www.glaukos.com). All forward-looking statements included in this press release are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on the forward-looking statements in this press release, which speak only as of the date hereof. We do not undertake any obligation to update, amend or clarify these forward-looking statements whether as a result of new information, future events or otherwise, except as may be required under applicable securities law.

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