AN ADVANCED DEVICE FOR GLAUCOMA THERAPY

iStent® TRABECULAR MICRO-BYPASS

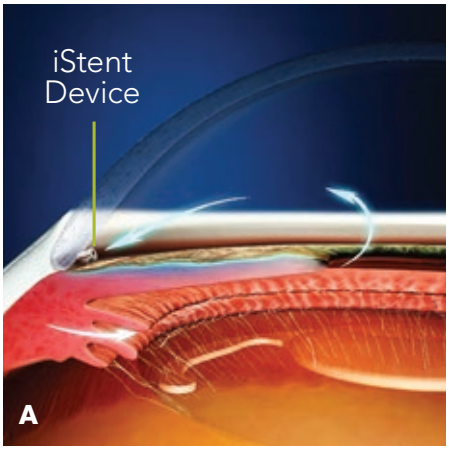
Cataract surgery and glaucoma therapy—all in one procedure.

iStent® is not only the world's smallest medical implant known to be implanted in the human body—it also started a revolution in glaucoma treatment as the first Micro-Invasive Glaucoma Surgery (MIGS) device approved by the FDA. Today iStent has been implanted in over 100,000 eyes around the world, with more and more patients benefiting from the iStent procedure every day.

HOW iSTENT WORKS

Implanted during cataract surgery, iStent works by creating a bypass between the front part of the eye and its natural drainage pathway to increase the flow of fluid (A). By creating a permanent bypass through the primary blockage site (trabecular meshwork), iStent is designed to:

- Improve the eye's natural fluid outflow to safely lower intraocular pressure
- Work continuously to improve the natural flow of fluid in the eye



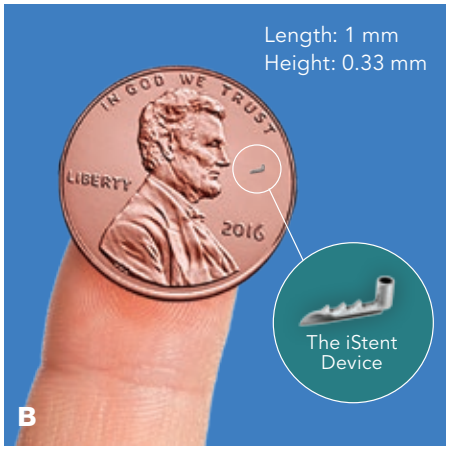
THE ADVANTAGES OF iSTENT

Adding iStent to cataract surgery can provide a number of benefits:

- Most patients are able to maintain normal eye pressure after the procedure
- Most patients experience a reduction in reliance on glaucoma medication (at discretion of eye care professional)
- iStent has an excellent overall safety profile
- iStent is covered by Medicare and most private insurance companies

THE iSTENT IMPLANT

Each tiny iStent implant (B) is comprised of a surgical titanium micro-bypass stent that's preloaded in a single use sterile inserter. The specially designed inserter helps the eye surgeon maneuver the implant for accurate, micro-targeted placement.



INDICATION FOR USE. The iStent® Trabecular Micro-Bypass Stent (Models GTS100R and GTS100L) 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 ≥ 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.

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