AN ADVANCED DEVICE FOR GLAUCOMA THERAPY

iStent *inject*®

Cataract surgery and glaucoma therapy—all in one procedure.

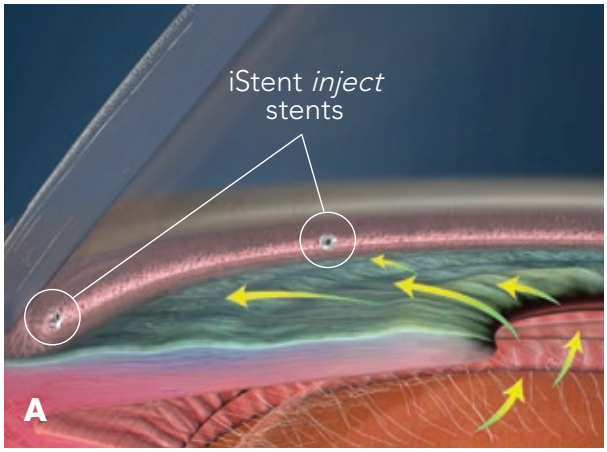
iStent *inject*®—a groundbreaking treatment option for patients with glaucoma undergoing cataract surgery—is made of two tiny stents believed to be the smallest medical device implanted in the human body. These tiny stents are designed to restore the eye's natural ability to drain fluid to help reduce increased eye pressure caused by glaucoma. Worldwide, iStent *inject* has helped countless patients, with more patients benefiting from the procedure every day.

THE ADVANTAGES OF iStent *inject*

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

- In clinical trials, most patients maintained healthy eye pressure for years after the procedure[1,2]
- iStent *inject* may help reduce the number of glaucoma medications needed, at your physician's discretion
- iStent *inject* has an excellent overall safety profile, similar to cataract surgery alone

HOW iStent *inject* WORKS



Implanted during cataract surgery, iStent *inject* works by creating two bypasses, or openings, between the front part of the eye and its natural drainage pathway to increase the flow of fluid (A). By creating two permanent bypasses through the primary blockage site (trabecular meshwork), iStent *inject* is designed to work continuously to improve the eye's natural flow of fluid to safely lower eye pressure.

THE iStent *inject* SYSTEM

iStent *inject* (B) includes two surgical-grade titanium stents that are preloaded in a single use sterile inserter. The specially designed inserter helps the eye surgeon maneuver the implant for accurate, micro-targeted placement.

REFERENCES: 1. iStent *inject*® Trabecular Micro-Bypass System: Directions for Use, Part # 45-0176. **2.** Hengerer FH. Personal Experience with Second-Generation Trabecular Micro-Bypass Stents in Combination with Cataract Surgery in Patients with Glaucoma: 3-Year Followup. ASCRS 2018 Presentation.

INDICATION FOR USE. The iStent *inject*® Trabecular Micro-Bypass System Model G2-M-IS 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* 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* 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 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 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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PM-US-0040