

ABOUT GLAUCOMA AND CATARACTS

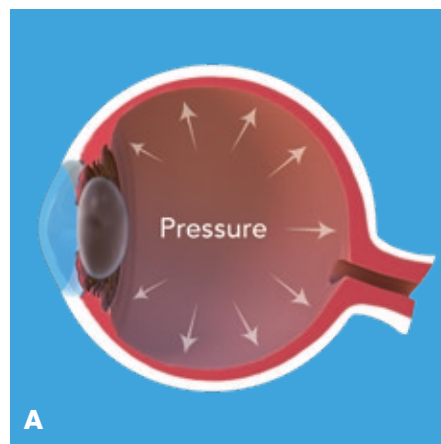
iStent
inject® w..

WHAT IS GLAUCOMA?

Glaucoma is a progressive disease of the eye that if left untreated can eventually lead to blindness. In the US, it is estimated that over three million people have glaucoma, many of which are undiagnosed.¹

About the Disease

- A major risk factor for glaucoma is increased eye pressure that occurs when fluid in the eye (A)—used to transport important nutrients to the lens and cornea—accumulates and cannot drain naturally.
- Over time the trapped fluid builds up, causing increased pressure in the eye, which can damage the optic nerve and destroy vision.
- The first sign of glaucoma is often loss of peripheral or side vision. Untreated glaucoma can lead to tunnel vision (B), and eventually can cause total blindness.
- Glaucoma can be grouped into two categories:
 - **Open-angle glaucoma:** Represents the majority of all glaucoma cases. Open-angle glaucoma is asymptomatic—meaning it occurs without noticeable symptoms appearing—and can often go undiagnosed without proper checkups, and worsen over time.
 - **Angle-closure glaucoma:** Less common but more severe, and is marked with a rapid rise in eye pressure and severe vision loss.



RISK FACTORS

Glaucoma is believed to be a genetic disease and may not appear until later in life. Besides hereditary factors, glaucoma can also be caused by a severe eye infection, a blunt eye injury or trauma, inflammatory eye conditions, or blockage of the eye's blood vessels. Other risk factors may include:

- Elevated eye pressure
- Sudden considerable changes in eye pressure
- Older age
- African American ethnicity
- Hispanic ethnicity
- Asian ethnicity
- Having a relative with glaucoma
- Decreased central corneal thickness
- Blunt eye trauma
- Inflammatory eye conditions

DIAGNOSIS AND TREATMENT

Since glaucoma comes with few warning signs, regular eye exams are important for detecting glaucoma early enough to allow successful treatment. A routine glaucoma exam usually includes a test to measure eye pressure and an examination of the eye, primarily the optic nerve. A visual field test may also be conducted to determine if there is any glaucoma damage, such as vision loss or blind spots in the field of vision.

Treatment Options

Glaucoma can be successfully treated, but early detection is vital, which is why most eye care professionals check for glaucoma during regular eye exams.

- **Prescription Eye Drops for Glaucoma:** The most common treatment for high eye pressure and glaucoma is prescription eye drops. When taken as directed, glaucoma eye drops reduce high pressure by decreasing the amount of fluid created within the eye or by helping the fluid drain from the eye.
- **Laser Treatments:** The most common laser treatment procedure, laser trabeculoplasty, helps drain fluid out of the eye. Occasionally, laser surgery can help eliminate the need for glaucoma eye drops, however in most cases, patients will need to continue taking glaucoma medicines after the procedures.
- **Micro-Invasive Glaucoma Surgery (MIGS) with iStent *inject*® W:** iStent *inject* W—one of the smallest medical devices known to be implanted in the human body—is made of two tiny stents that are designed to restore your eye’s natural ability to drain fluid out of the eye to reduce intraocular pressure. Designed for cataract patients with glaucoma, iStent *inject* W is implanted at the time of cataract surgery.

ABOUT CATARACTS

A cataract is formed when the eye’s natural lens stiffens and hardens. As this happens, a small area of the lens begins to cloud up, making it harder to see. Over time, this clouding can get worse, putting one’s vision at risk.

- Cataracts impact people with and without glaucoma
- In the U.S. approximately 1 in 5 cataract patients also have glaucoma²
- Only adult patients that have both cataracts and open-angle glaucoma are eligible for iStent *inject* W



REFERENCES: 1. 2017 Market Scope Glaucoma Report, data on file. 2. Medicare Administrative Claims Data (Carrier 5% SAF) 2007-2010.

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, retrolubar 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 \geq 2 lines \geq 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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