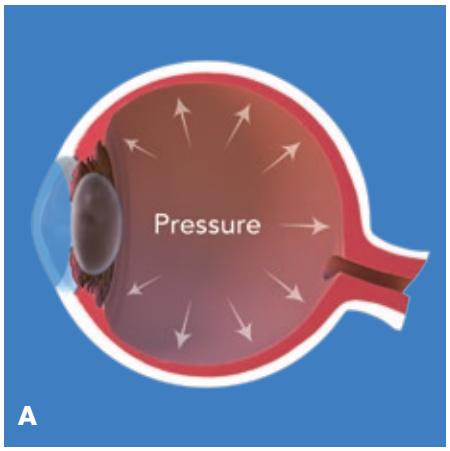
ABOUT GLAUCOMA AND CATARACTS

iStent® TRABECULAR MICRO-BYPASS

WHAT IS GLAUCOMA?

Glaucoma is a progressive disease of the eye that if left untreated can eventually lead to blindness. In the US, over three million people have glaucoma, with an estimated 120,000 going blind each year.[1,2]



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—accumulates and cannot drain naturally.
- Over time the trapped fluid builds up, causing 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:** accounts for approximately 70% to 90% of all 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

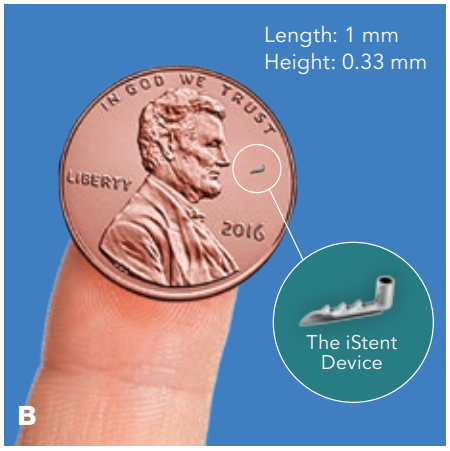
DIAGNOSIS AND TREATMENT

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®:** iStent is a tiny medical implant—the smallest known to be implanted in the human body—that is designed to restore the eye's natural ability to drain fluid out of the eye to reduce glaucoma pressure. The first MIGS device approved by the FDA, iStent is designed for patients with cataracts and glaucoma, and 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 glaucoma[3]
- Only adult patients that have both cataracts and open-angle glaucoma currently being treated with glaucoma medication are eligible for an iStent

REFERENCES:

1. The Eye Diseases Prevalence Research Group, *Arch Ophthalmol.* 2004; Prevent Blindness America **2.** National Institutes of Health; Quigley and Vitale, *Invest Ophthalmol Vis Sci.* 1997 **3.** Medicare Administrative Claims Data (Carrier 5% SAF) 2007-2010.

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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