

## INFORMED CONSENT FOR ISTENT SURGERY

You have glaucoma. Glaucoma is a disease defined by optic nerve damage. The optic nerve connects the eye to the brain. The damage to the optic nerve in glaucoma is thought to be caused by fluid imbalance or pressure in the eye. Glaucoma slowly gets worse over time and cannot be reversed. If it is not treated, it causes a painless loss of eyesight. In some cases, it can lead to blindness.

**Alternatives (choices and options).** The best choices for glaucoma treatment are those that lower the eye pressure with the fewest risks to the patient's eyesight and overall health.

- Usually eye drop medications or laser therapy are used first. Often, multiple medications are needed to get the desired pressure level.
- If medications and laser treatment do not work well enough, or if patients have trouble using eye drops because of cost, side effects, and other difficulties, then glaucoma surgery is required. There are many types of glaucoma surgery.
- You can decide to have no treatment. Without treatment, your glaucoma will get worse and you will lose more vision. You may even go blind.

Your ophthalmologist (eye surgeon) is recommending iStent surgery. This is a new type of glaucoma surgery called "minimally-invasive glaucoma surgery" (MIGS). MIGS alters the eye's drainage system to lower the eye pressure and reduce the need for medications. MIGS has fewer complications than traditional glaucoma surgeries. MIGS is performed through an incision that is less than 3mm long (smaller than 1/8 of an inch). Your ophthalmologist will implant a device, the iStent Trabecular Microbypass Stent, in an area of the eye called Schlemm's Canal. The stent is made of inactive titanium and allows fluid to leave your eye. It is safe to have an MRI with an iStent in your eye.

**Benefits (how the surgery can help).** The goal of iStent surgery is to lower your eye pressure and help you keep the vision you have now. It will not bring back vision you have already lost from glaucoma.

**Risk (problems the surgery can cause).** As with any surgery, there are risks with iStent surgery. In some cases, the surgery may not lower your eye pressure or control your glaucoma even when it is properly performed. Your ophthalmologist cannot tell you about every risk. Here are some of the most common and serious risks:

- Failure to control eye pressure, with the need for eye drops, laser, or another surgery
- Abnormal collection of fluid in the eye, with the need for another surgery
- Worse or lost vision
- Pressure that is too low
- Damage to the eyeball
- Infection / bleeding in the eye
- Inflammation
- Pain, irritation, or discomfort in the eye or surrounding tissues that may persist
- Drooping of eyelid
- Double vision

- Problems during surgery that need immediate treatment. Your surgeon may need to do more surgery right away or change your surgery to treat this new problem.
- Other risks. There is no guarantee that the surgery will improve your vision. The surgery or anesthesia might make your vision worse, cause blindness, or even the loss of an eye. These problems can appear weeks, months, or even years after surgery.
- Careful follow-up is required after surgery. After your eye heals, you will still need regular eye exams to monitor your glaucoma and watch for other eye problems.

**IStent can be performed under topical or regional anesthesia.** With either type of anesthesia, the anesthesiologist, ophthalmologist, or nurse anesthetist may also give you an intravenous sedative to help you relax.

- With topical anesthesia, eye drops are used to numb the eye. You must be able to cooperate with the ophthalmologist to make sure you do not move your eye during surgery. Risks of topical anesthesia include injury to the eye by movement during surgery, drooping of the eyelid, and increased sensation during the surgery.
- With regional anesthesia, anesthetic medicine is injected around the eye to numb the
  eye and keep it from moving. Risks of regional anesthesia include needle damage to the
  eyeball or optic nerve, which could cause vision loss; interference with circulation of the
  retina, which could cause vision loss; drooping of the eyelid, double vision, and bruising
  of the skin around the eyes.
- Intravenous sedation can cause heart and breathing problems. In rare cases, it can cause death.

## By signing below, you consent (agree) that:

- You read this informed consent form or had it read to you.
- You were told you have glaucoma.
- Your questions about the surgery were answered.
- You consent to have the ophthalmologist perform iStent surgery on the \_\_\_Right \_\_\_Left eye.

Patient Signature (or authorized to sign)	 Date	
PRINTED Patient Name / Authorized to Sign Name		