**THIS IS A SAMPLE CONSENT FORM. REVIEW AND REVISE AS NEEDED.**

**Keep each section together on the same page: move it as needed.**

**Remove the section in red.**

**Add your letterhead to the first page of the consent form.**

**Change font size for large print.**

**Version 2/21/20**

**Informed consent for Xen Microstent surgery**

You have glaucoma. Glaucoma is a disease defined by optic nerve damage. The optic nerve connects the eye to the brain. Fluid imbalance or eye pressure problems damage the optic nerve. 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) recommends Xen Microstent surgery.** Xen Microstent is a new type of glaucoma surgery called “minimally-invasive glaucoma surgery” (MIGS). MIGS provides control of the eye pressure at lower risk than more traditional glaucoma surgeries. It alters the eye’s drainage system to lower the eye pressure and reduce the need for medications. MIGS is performed through an incision that is less than 3 mm long (smaller than ¼ of an inch). Your surgeon will implant the Xen Microstent in the sclera (the white wall of the eye). The stent is made of gelatin-like material the size of an eyelash. The gelatin comes from pigs. Fluid leaves the eye through the stent and your eye pressure goes down. The fluid collects under your upper eyelid in a structure called a bleb. It is then absorbed into your blood stream.

**Anti-scarring medication is used at the time of surgery to keep scar tissue from forming.** Scar tissue can also block the stent after surgery. If that happens, your ophthalmologist may recommend an injection of more anti-scarring medication or a surgery to fix the bleb so fluid flows again. Mitomycin-C (MMC), 5-Fluorouracil (5FU), and Avastin (bevacizumab) are the most commonly used anti-scarring medications. MMC is approved by the Food and Drug Administration (FDA) for use in eye surgery. 5FU and Avastin were originally approved by the FDA for cancer treatment. However, physicians can use FDA-approved drugs for other purposes (this is called “off-label” use). These medications should not be used in women who are pregnant, planning to become pregnant or nursing.

**Benefits (ways the surgery can help).** The goal of Xen Microstent 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 Xen Microstent. 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 treatment, 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
* Cataract (except if you have already had cataract surgery or if you are having cataract surgery at the same time as this glaucoma surgery)
* Pain, irritation, or discomfort in the eye or surrounding tissues that may last
* 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. It is possible that the surgery or anesthesia may 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.

**Xen Microstent surgery is performed under regional anesthesia.** Anesthetic medicine is injected around the eye to numb the eye and keep it from moving. The anesthesiologist, ophthalmologist, or nurse anesthetist may also give you intravenous sedation to help you relax.

* 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 Xen Microstent surgery on your \_\_\_\_\_\_\_\_\_\_\_ (“right,” “left”) eye.

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Patient Signature (or person authorized to sign for patient) Date