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Informed consent for canaloplasty 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 pressure problems in the eye damages the 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.

There are new types of glaucoma surgery called "minimally-invasive glaucoma surgery" (MIGS). Canaloplasty is one of them. MIGS controls eye pressure with fewer complications than traditional glaucoma surgeries. It alters the eye's drainage system to lower the eye pressure and reduce the need for medications. The surgery is performed through an incision that is less than 3 mm long (smaller than 1/8 of an inch). Your ophthalmologist will inject a non-toxic jelly to inflate and stretch parts of your eye's drainage system (the trabecular meshwork, Schlemm's Canal, and collector channels). This will allow fluid to leave your eye and lower the eye pressure.

Benefits (how the surgery can help). The goal of canaloplasty 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 surgical procedure, there are risks with canaloplasty surgery. 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
- Pain, irritation, or discomfort in the eye or surrounding tissues that may last •

Drooping of the 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 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.

Canaloplasty can be performed under topical or regional anesthesia. With either type of anesthesia, the anesthesiologist, ophthalmologist, or nurse anesthetist may also give you 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 procedure.
- With regional anesthesia, anesthetic medicine is injected around the eye to numb the eye and immobilize it for surgery. 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 canaloplasty surgery on your

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



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Informed Consent for GONIOTOMY

Dr. _____ has discussed with me this procedure as briefly summarized here:

Glaucoma is a chronic disease causing optic nerve damage as a result of a fluid imbalance (intraocular pressure) in the eye as well as possible alterations in blood flow to the optic nerve. It is slowly progressive and nerve damage is irreversible. Left untreated, glaucoma usually causes a painless loss of eyesight. It is well established that lowering the intraocular pressure can slow the process of optic nerve damage. The degree of pressure lowering necessary to prevent optic nerve damage is different for each person and each eye. The greater the optic nerve damage, the lower the intraocular pressure must be to achieve stability and prevent further damage and vision loss.

The **purpose** of the proposed procedure is to improve the outflow of fluid from your eyes and therefore reduce the risk of future vision loss to glaucoma. After Goniotomy, many patients are able to better control their eye pressure with fewer medications.

The **nature** of the procedure involves incising through a portion of the drainage area of your eye, known as the trabecular meshwork to improve aqueous outflow. This surgery is usually performed in conjunction with cataract surgery.

Risks and possible consequences of the proposed procedure:

- Treatment may not accomplish the desired objective(s).
- Despite successful surgery, the eye may continue to be damaged by glaucoma.
- Treatment may result in an increase in intraocular pressure, or excessive lowering of intraocular pressure, infection, abnormal collection of fluid in the eye necessitating further surgery, bleeding in the eye, chronic inflammation, cataract or secondary cataract, retinal detachment, droopy eyelid, irritation or discomfort in the eye that may resolve or persist, and vision could be worsened by treatment..

I am aware that, in addition to the risks specifically described above, there are **other risks related to the performance of any surgical procedure**, such as infection, cardiopulmonary arrest, respiratory difficulties, injury to adjacent organs or structures, unanticipated allergic reaction to substances and pressure/position related injuries.

I have been advised of all reasonable **alternatives** to this treatment, including risks, probable effectiveness of each and the likely consequences of not having this proposed treatment. Alternatives to this treatment are: using eyedrops to control pressure, laser treatment(s), trabeculectomy or doing nothing.

I acknowledge that **no guarantees** have been made to me as to the results of the procedure(s) and I am also aware that complications and risks may occur despite precautions.

If, in the course of the above-noted procedure Dr. _____ deems it necessary or advisable to proceed differently than planned, I consent to the performance of unplanned procedure(s) in addition to or different from those described herein.

I consent to the administration of such anesthetics as Dr. _____ may consider appropriate. I understand that all types of anesthesia involve some risk.

I certify that I have read or have had the above information read to me and that I understand it. All of my questions have been answered to my satisfaction. I hereby give my informed and voluntary consent for Dr. _____ to perform Goniotomy surgery on my _____.

Patient Signature: _____ Witness Signature: _____ Date: _____