

## DURYSTA (Bimatoprost Implant) - INFORMED CONSENT

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 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.

Your surgeon recommends treating your glaucoma with the DURYSTA implant. The implant contains a medication called bimatoprost that has been used for a long time to help lower eye pressure. Durysta is used to treat primary open-angle glaucoma and ocular hypertension; the purpose of the medication is to lower your eye pressure and help you keep the vision that you have now. It will not bring back the vision you may have already lost from glaucoma

### PROCEDURE

The ophthalmologist will numb the eye so that you do not feel pain. The ophthalmologist will then use a microscope to carefully inject the implant into the anterior chamber (front part of the eye). You must remain upright (sitting or standing) for 1 hour after the injection. The implant stays in your eye and releases the medicine for about 4 to 6 months while it slowly dissolves.

### ALTERNATIVES

The best choices for glaucoma treatment are those that lower eye pressure with the fewest risks to eyesight and overall health. Usually eye drop medications or laser surgery 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. You can decide to have no treatment. However, without treatment, your glaucoma will get worse and you will lose more vision. You may even go blind.

### MEDICATIONS

You may need to use drops both before and after treatment. Pressure in the eye may temporarily go up after treatment. If the pressure does elevate, you may need additional medicines to lower the pressure, which will be administered in the office. Rarely, the pressure in the eye could elevate to a level that may require surgery in the operating room to relieve the glaucoma. You may need to use drops afterwards to help the eye heal correctly. The doctor will monitor and advise you on continuing use of your previous medications after the procedure.

### RISKS AND COMPLICATIONS

Any implant procedure has risks and the potential for complications. Many patients experience some minor problems right after the injection. Your vision might be blurry right after the injection; do not drive or use machines until your vision gets better. Your eye may be irritated and make a lot of tears for a few hours. In addition, the white part of your eye might turn bright red. This is from a small amount of bleeding on the surface of your eye; it will not change how well you see and will clear up in a few days or a week.

There are risks with the medication, the injection, and the implant. Risks from the medication include failure to control eye pressure, with the need for eye drops, laser treatment, or glaucoma surgery, worse or lost vision, edema (swelling) in the back of your eye causing blurry vision, permanent pigmentation: increased brown coloring of the iris (colored portion of the eye), and inflammation, which could make glaucoma or uveitis worse. Risks from the injection include damage to the eyeball, infection that may occur days to weeks after the injection, bleeding in the eye, pain, irritation, or discomfort in the eye or surrounding tissues that may not go away. Risks

from the implant including the possibility of losing some cells from the inner layer of your cornea (the clear tissue at the front of your eye); if you lose many cells, you could lose vision. In addition, the implant could move to a different part of your eye. You might need surgery to move or remove the implant.

The Food and Drug Administration (FDA) recommends only one DURYSTA implant per eye. Multiple implants could increase the risk of losing cells from the cornea, which could lead to vision loss. Your ophthalmologist will talk to you about this risk if more than one implant is recommended.

Tell the ophthalmologist right away if you notice any other problems after the injection. Call if you have eye pain, blurry or decreased vision, extra sensitivity to light, eye redness, or pus or discharge coming from the eye.

### RETREATMENT CONSENT

Your ophthalmologist recommends an additional implant. You understand that the FDA feels only one implant should be used. You may lose cells in your cornea, and have worse vision. The long-term risk of having another implant is unknown.

By signing below, you agree that:

- You read this informed consent, or someone read it to you.
- You have been told you have glaucoma.
- You understand the information, including the risks, benefits and alternatives to the procedure.
- Dr. Harvey and/or his staff offered you a copy of this informed consent form.
- Dr. Harvey and/or his staff answered your questions about the Durysta procedure.

I consent to have another Durysta injection in my                      **RIGHT eye**                      **LEFT eye**                      **BOTH eyes.**

Signature \_\_\_\_\_ Date \_\_\_\_\_ Witness \_\_\_\_\_