INSTRUCTIONS 11/29/18

* Place on your letterhead.
* Make any changes to this sample letter needed to meet the needs of your patients.
* Send the letter via regular mail.
* Send a copy to the referring ophthalmologist or optometrist.
* Place a copy in the patient’s medical records.

Dear [name of patient],

I am writing to you about the CyPass device that was placed in your eye during your surgery. CyPass is a small tube with tiny holes. It is used to drain fluid that can cause high eye pressure and possible vision loss in people with glaucoma.

**The Food and Drug Administration (FDA) has issued a recall of this device.** The FDA explained that CyPass might harm the cornea, which is the clear outer layer of the eye. This letter explains more about CyPass and how I will check your eye for problems.

You need to know more about your cornea to understand why the FDA recalled CyPass. As people age, they naturally lose some cells in the inner layer of the cornea. This is called endothelial cell loss or ECL. This cell loss also happens after eye surgeries like cataract surgery with or without the CyPass device.

Studies must be done before the FDA approves medical devices. Patients who had CyPass placed during their cataract surgery were studied for 2 years to watch for ECL. CyPass patients had the same amount of ECL as patients who only had cataract surgery. The FDA approved the CyPass device in 2016.

Patients with CyPass were watched for a few more years. Alcon and the FDA announced that some of these patients had more ECL than expected at 5 years after surgery. This extra ECL might cause vision loss. This is why the FDA recalled CyPass.

**Please call our office to make an appointment.** I will check your eyes and the CyPass device for problems. We will then discuss if anything needs to be done for you.

We hope this information is helpful. Please call us if you have any questions.

Sincerely,

[Name of ophthalmologist]

Cc [Name of referring ophthalmologist or optometrist]