

# PATIENT INFORMATION BROCHURE



Caution: Federal law restricts the CyPass system to sale by, or on the order of, a physician.

## PATIENT INFORMATION BROCHURE

### CyPass® System

This brochure has been written to help you and your eye surgeon make an informed decision about management of your glaucoma. One option is the CyPass® Micro-Stent, a device implanted in the eye at the time of cataract surgery to help reduce your eye pressure. This brochure will help you to decide if the CyPass® Micro-Stent would be a good option for you.

#### **What is glaucoma?**

Glaucoma is a disease that causes damage to the optic nerve in your eye. If glaucoma is not treated, it can cause vision loss that gets worse over time. Like many diseases, the symptoms of glaucoma can be subtle at first, such as a slight loss of peripheral vision (side vision). If left untreated, glaucoma may lead to significant vision loss over time.

There are many types of glaucoma. The most common is called primary open angle glaucoma. The CyPass Micro-Stent is specifically for patients with this particular type of glaucoma.

#### **How is intraocular pressure related to glaucoma?**

Eye pressure is often measured by eye surgeons in order to see if you might have glaucoma, even if you have not yet had any vision loss.

Your eyes are constantly producing fluid. This fluid provides nourishment to the eye and is essential for normal, healthy eye function. As fluid is produced, it moves throughout your eye and eventually exits through tiny drainage channels located near the cornea (the front part of your eye). If these drainage channels become blocked, the fluid in your eye can build up, causing elevated eye pressure. This elevated eye pressure can damage your optic nerve.

#### **What is the CyPass System?**

The CyPass System consists of the CyPass Micro-Stent and CyPass applier, which is an instrument used by your eye surgeon to implant the CyPass Micro-Stent in your eye.

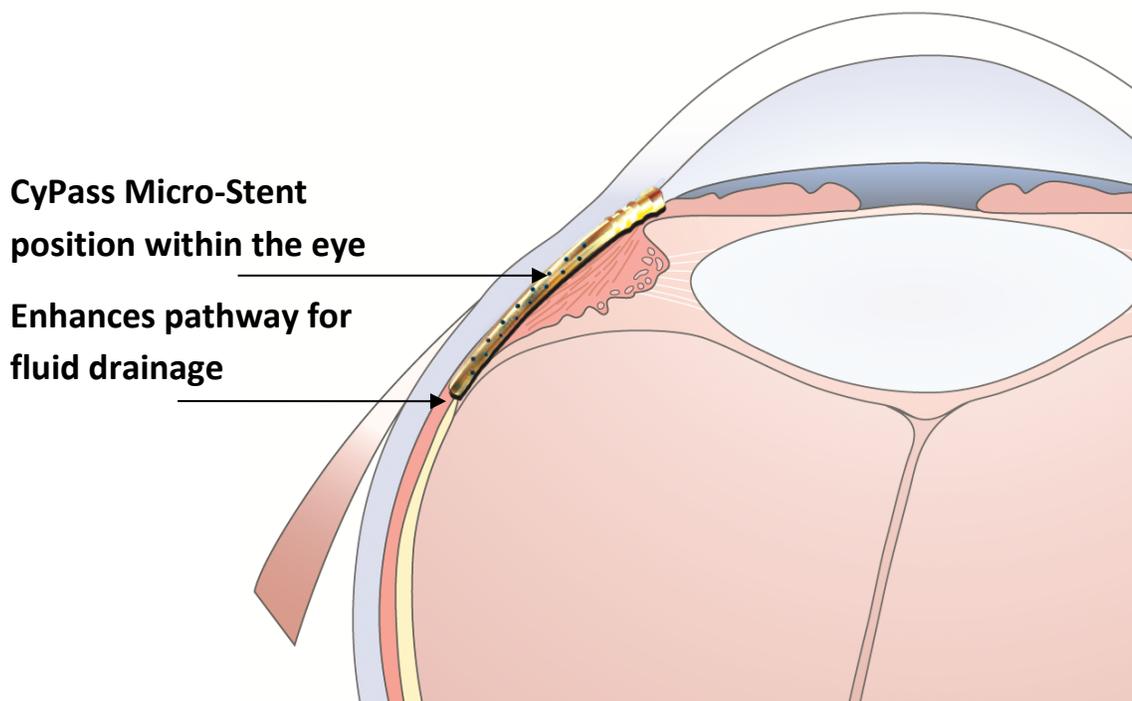
The CyPass Micro-Stent is a very small, specially designed plastic tube that is implanted by your eye surgeon into a specific location in the eye. Figure 1 shows you the size of the CyPass Micro-Stent compared to a dime. The CyPass Micro-Stent is implanted in the eye at the time of cataract surgery to help reduce your eye pressure.



**Figure 1** – CyPass® Micro-Stent on Top of a Dime

### **How does the CyPass Micro-Stent work?**

The CyPass Micro-Stent works by enhancing one of the natural drainage pathways for the fluid in your eye. The Micro-Stent allows fluid to pass through and keeps the pathway open. This can help to provide control of your eye pressure. Figure 2 is a picture of the CyPass Micro-Stent implanted within the eye.



**Figure 2 – Drawing of Eye with CyPass® Micro-Stent**

### **When is the CyPass Micro-Stent implanted?**

If the natural lens in your eye becomes cloudy, you may need to have cataract surgery to replace the natural lens with an intraocular lens (IOL). When you have cataract surgery with the CyPass system, the CyPass Micro-Stent is implanted in your eye immediately after your cataract removal and IOL implantation, as a single procedure. The eye surgeon implants the CyPass Micro-Stent through the same surgical incision used to remove your cataract.

### **What steps do I need to take before surgery?**

Your eye surgeon may ask you to stop or start taking certain medications for a few days before your surgery. Talk to your eye surgeon about any other recommendations.

### **What is cataract surgery?**

After you and your eye surgeon have decided that you will have your cataract removed, your eye will be measured. This will determine the suitable IOL for you that will be implanted in your eye during surgery.

When you arrive for surgery, you will be given eye drops and perhaps medicines to help you relax. Cataract surgery techniques vary widely. However, the eye is always numbed to make the operation painless. To perform surgery, your eye surgeon will use a microscope to have a magnified view of your eye. Your natural lens sits in a bag-like structure called the capsule. The capsule is located just behind the colored part of your eye (iris). A small incision is made in the outer surface of the eye to remove the cataract. An IOL is then implanted into the capsule to replace your natural lens that your eye surgeon has just removed. The IOL will act in the same way as your natural lens once did to focus images clearly onto the back of your eye (retina), to allow clear vision once again. The eye surgeon will usually place a shield over your eye after surgery. You will be ready to go home after a short stay in the outpatient recovery area. You should plan to have someone else drive you home.

### **How is the CyPass Micro-Stent implanted?**

If you receive the CyPass Micro-Stent, after your cataract has been removed and the IOL is implanted, your eye surgeon will look into your eye to confirm the location where the CyPass Micro-Stent will be implanted. The CyPass Micro-Stent will be implanted in your eye through the same incision used for your cataract surgery. When CyPass Micro-Stent implantation is completed, the eye surgeon will usually perform the same steps as after cataract surgery – a shield will be placed over your eye and you will be ready to go home after a short stay in the outpatient recovery area. You should plan to have someone else drive you home.

### **What should I expect after surgery?**

Your eye surgeon will give you eye drops to speed up the healing process and to prevent infection. You will return home after surgery. Typically, your eye surgeon will examine you the following day. Your eye pressure may fluctuate in the first several days after surgery. The specifics of surgery may be different for each individual. Be sure to consult your eye surgeon so you can fully understand the recovery process after the cataract surgery with CyPass Micro-Stent.

You should be given a Patient Identification card with important information about the CyPass Micro-Stent you have received. You should keep the card in a safe place, such as your wallet, for future reference. This Patient Identification card should be shown to your current and future healthcare providers.

### **What are the alternative treatment options for glaucoma?**

Other than the CyPass Micro-Stent, treatment options include:

- Prescription eye drops
- Laser treatment
- Surgeries to clear the blockage of fluid drainage channels, such as trabectome, canaloplasty, viscocanalostomy or trabeculotomy
- Trabecular bypass surgery (insertion of a stent to improve drainage of fluid by going around the blocked fluid drainage channels)

- Trabeculectomy surgery to create an opening that allows fluid to drain out of the eye
- Implantation of shunts or fluid drainage tubes to create an opening that allows fluid to drain out of the eye

### **What are the potential benefits of receiving the CyPass Micro-Stent?**

Use of the CyPass Micro-Stent in conjunction with cataract surgery may help you manage your glaucoma by lowering your eye pressure. In a clinical study conducted in the United States (U.S.), 374 patients received the CyPass Micro-stent at the same time as cataract surgery and 131 patients had only cataract surgery. Patients were followed for 2 years after their surgery. For each 100 patients in the study, about 73 patients who received the CyPass Micro-Stent and cataract surgery experienced significant lowering of their eye pressure, while about 58 patients who received only cataract surgery experienced similar results.

### **What are the potential risks associated with CyPass Micro-Stent implantation?**

As with any surgery, there are risks and potential complications associated with routine cataract surgery and CyPass implantation. The risks of CyPass Micro-Stent implantation with cataract surgery are similar to the risks of having only cataract surgery; however, there are some additional risks associated with CyPass Micro-Stent implantation that were reported in a small number of patients. General surgery risks include reactions to medicines, bleeding, infection, inflammation, vision changes, increased eye pressure and cloudiness of the cornea (the clear front window of your eye) that might require replacement of the cornea (corneal transplant). Please discuss these general surgical risks with your eye surgeon.

There is a small risk that the CyPass implantation is not successful or the device is not properly positioned in your eye. The CyPass Micro-Stent may become blocked or may move from its original position. You may need to have a second surgery to reposition the CyPass Micro-Stent, to trim the end of the CyPass, to clear CyPass blockage, to reduce fluid flow through the CyPass, or to remove the device. If this happens, you might lose some of the inner layer of cells in your cornea. Because these cells are needed to keep the cornea clear and maintain clear vision, your eye surgeon may periodically take pictures of your eye to check for cell loss. In the clinical study of the CyPass Micro-Stent, a higher rate of cell loss and second surgeries were reported in a small number of patients where the CyPass was not properly positioned.

Although these have not been reported frequently, other additional risks that may be related to use of the CyPass Micro-Stent include bleeding during surgery, inflammation, tissue trauma, fluid collection in the back of the eye, changes in your eye pressure that could affect your vision, the feeling that there is something in your eye, pain in your eye, glaucoma disease progression, and the IOL may move from its original position. Unplanned second surgeries may be needed to address these additional risks.

Your eye surgeon will monitor you after surgery to make sure your eye pressure is controlled. If it is not, your eye surgeon may recommend appropriate medication or other treatment to control your eye pressure.

Please discuss all risks and benefits with your eye surgeon before your surgery.

The safety and effectiveness of the CyPass Micro-Stent has not been established in patients with the following circumstances or conditions:

- Eyes with significant prior trauma
- Eyes in which the front of the eye is abnormal
- Eyes with chronic inflammation
- Eyes with glaucoma that have had prior cataract surgery
- Eyes with glaucoma associated with vascular disorders
- Eyes with uveitic glaucoma (glaucoma associated with inflammation in your eye)
- Eyes with pseudoexfoliative glaucoma (glaucoma caused by a build-up of a white dandruff-like material in the eye) or pigmentary glaucoma (glaucoma caused by flaking off of pigment granules that normally adhere to the back of the colored part of the eye)
- Eyes with secondary open angle glaucoma
- Eyes that have undergone prior surgery to treat glaucoma (surgery may have involved an incision or may have involved cryotherapy or cyclodiode therapy)
- Eyes with pressure less than 21 mmHg or greater 33 mmHg that are not using glaucoma medication
- Eyes with pressure greater than 25 mmHg that are using glaucoma medication
- Eyes in which cataract surgery complications occurred
- When CyPass Micro-Stent is implanted without cataract surgery
- 21 years of age or younger

The safety and effectiveness of use of more than a single CyPass Micro-Stent has not been established. The CyPass Micro-Stent has not been shown to be an alternative to treatment of glaucoma with medicine.

### **Is the CyPass Micro-Stent right for me?**

The CyPass Micro-Stent may be right for you if:

- you have glaucoma that is not severe, and
- you are planning to have surgery to remove your cataract

The CyPass Micro-Stent should not be used if:

- you have a type of glaucoma other than primary open angle glaucoma,
- your eye anatomy or condition is unusual. Your eye surgeon will examine your eye and let you know if there is anything unusual about your eye's anatomy or condition; for instance, if the area in your eye is too narrow to implant the CyPass Micro Stent, or if there is a condition that may prevent your eye surgeon from seeing where the CyPass Micro-Stent will be implanted.

### **Has the CyPass Micro-Stent been studied?**

Yes. In the United States, a study looked at the safety and effectiveness of the CyPass Micro-Stent in lowering eye pressure in patients with primary open angle glaucoma who were undergoing cataract surgery. In this study, 374 patients received the CyPass Micro-stent at the same time as cataract surgery, and 131 patients had only cataract surgery. Patients with CyPass Micro-Stent and cataract

surgery achieved a significant lowering of their eye pressure more often than patients who only had cataract surgery. This lowered eye pressure lasted through the 2 year-long study.

In this study, a slightly different instrument was used to implant the CyPass Micro-Stent than the one that would be used for your surgery. The safety of the instrument that would be used to implant the CyPass Micro-Stent during your surgery was evaluated in a separate study. Study results showed that the safety performance of the 2 instruments was similar.

**What other symptoms have patients reported after surgery?**

Patients who participated in the clinical study were asked to complete a questionnaire about different eye symptoms during the course of the study. Some patients experienced worsening of some of these symptoms. This was reported for a small number of patients who had cataract surgery and CyPass Micro-Stent implanted, as well as for patients who only had cataract surgery. Many of these patients had other eye conditions that may have contributed to their symptoms. Because the questionnaire used was not developed with input from patients, the true rates for symptoms may be different from the rates seen in this study. However, the rates of symptoms that got worse in the study are shown in Table 1.

**Table 1: Rates of Worsening for Eye Symptoms through 2 Years after Surgery in the U.S. Clinical Study of the CyPass System**

	<b>Cataract Surgery and CyPass</b>	<b>Cataract Surgery Alone</b>
	<i>Number of Patients Out of 100</i>	<i>Number of Patients Out of 100</i>
Halos (rings around lights)	3	2
Blurred vision	2	2
Dry eye	1	1
Eye pain	1	1
Glare (trouble seeing street signs due to bright light or oncoming headlights)	3	2
Foreign body sensation (feeling that something is in your eye)	1	1
Any eye symptom	6	3

Symptoms counted as worsening if they were two levels worse than they had been at the beginning of the study and categorized as “severe” or “very severe”. Symptoms related to conditions that were present before they started the study were not counted.

Shown in Table 2 are symptoms that were “severe” or “very severe” at any time during the study, even if they didn’t get worse during the study.

**Table 2: Rates of Severe or Very Severe Eye Symptoms through 2 Years after Surgery in the U.S. Clinical Study of the CyPass System**

	<b>Cataract Surgery and CyPass</b>	<b>Cataract Surgery Alone</b>
	<i>Number of Patients Out of 100</i>	<i>Number of Patients Out of 100</i>
Halos (rings around lights)	4	2
Blurred vision	4	5
Eye pain	2	2
Glare (trouble seeing street signs due to bright light or oncoming headlights)	7	12
Foreign body sensation (feeling that something is in your eye)	2	4

Symptoms are included if they were categorized as “severe” or “very severe”, even if they didn’t get worse during the study or were related to conditions that were present before the study started.

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