Hydrus® Microstent

Patient Information Brochure

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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PATIENT INFORMATION BROCHURE

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This brochure will help you and your eye surgeon decide whether to implant the Hydrus® Microstent in your eye at the time of cataract surgery. The Hydrus Microstent may help reduce your eye pressure.

GLAUCOMA AND YOUR OPTIC NERVE

Glaucoma is an eye disease that damages the optic nerve of the eye. It can result in vision loss and blindness. In the early stage of glaucoma, symptoms may not be noticeable, such as slight changes to your side vision. If not treated, vision loss may get worse.

PRIMARY OPEN-ANGLE GLAUCOMA AND YOUR EYE PRESSURE

Among the many types of glaucoma, the most common is primary open-angle glaucoma (POAG). The Hydrus Microstent is specifically for patients with POAG. Fluid produced in your eye provides nourishment to the front part of your eye. The fluid drains through a spongy meshwork that is located near the edge of the iris (the color portion of your eye). If fluid from the front part of the eye does not drain properly, it can cause elevated eye pressure (IOP) in the back of the eye (optic nerve). The exact cause of POAG is unclear, but elevated IOP is the strongest risk factor for glaucoma. Figure 1 shows how elevated IOP may damage the optic nerve and result in vision loss.

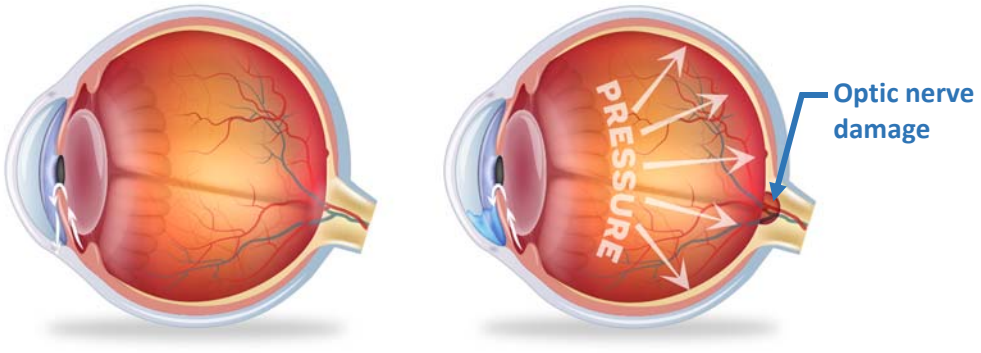

Figure 1: Eye pressure and optic nerve damage

THE HYDRUS MICROSTENT AND HOW IT WORKS

The Hydrus Microstent is an implantable metallic device that is attached to an inserter, also called a delivery system. The inserter is a hand-held instrument used by your eye surgeon to implant the microstent in your eye.

The Hydrus Microstent works by improving the flow of fluid from the front of your eye through part of the spongy meshwork and into a fluid drainage channel called Schlemm's canal located at the edge of the iris. The microstent maintains the opening of the drainage pathway along the length of the implant. This allows fluid to pass through the drainage pathway which may help control your eye pressure. Figure 2 shows the Hydrus Microstent implanted within Schlemm's canal and how fluid drains through it.

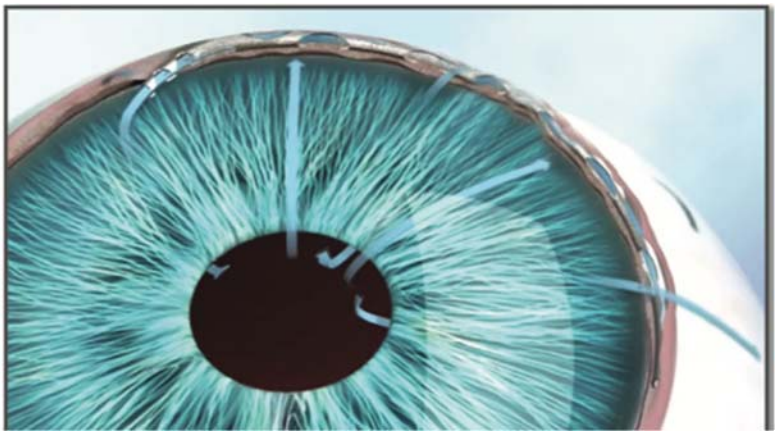

Figure 2: Hydrus Microstent implanted in Schlemm's canal and opening the fluid pathway

The Hydrus Microstent is very small. Figure 3 shows the size of the microstent compared to a quarter. When it's implanted in your eye it will not be visible to you or others without special eye examination equipment.

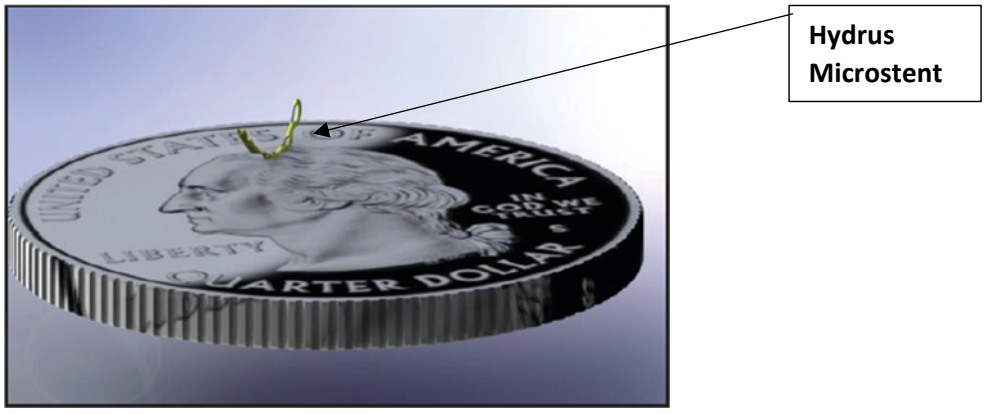

Figure 3: Hydrus Microstent on top of quarter

You may be a candidate for the Hydrus Microstent if you have a cataract and you have mild to moderate POAG. You may not be a candidate for the Hydrus Microstent if you have an unusual

anatomy or a condition that makes it difficult for your eye surgeon to implant it. Your eye surgeon can answer questions and help you to determine if you are a candidate for the Hydrus Microstent.

CATARACT SURGERY AND THE HYDRUS MICROSTENT

Your natural lens is located behind the iris (colored part of your eye). The lens is contained in a thin bag-like structure called the capsule. If your lens becomes cloudy (a cataract), it can be removed and replaced with an intraocular lens (IOL) to improve your vision. A small incision is made in your cornea (transparent layer forming the front of your eye also called the anterior chamber) to remove the cataract and implant the IOL.

Immediately after your cataract surgery, while your eye is still numbed, your eye surgeon will use the inserter to implant the Hydrus Microstent. Your eye surgeon will implant the microstent using the same incision in the cornea used for your cataract surgery.

SURGICAL INFORMATION

Before your surgery day, you may be asked to stop and/or start certain medications for several days prior to surgery.

On the day of surgery, you will be given eye drops and may be given medicine to help you relax. Your eye will be numbed to make the operation painless. Your eye surgeon will have a magnified view of your eye using a microscope to perform the surgery. After surgery, an eye shield may be placed over your operated eye. You will be given eye drops to aid in the healing process and to prevent infection in your eye. You can go home after a short recovery period. You should plan to have someone drive you home.

Typically, you will be examined the following day. Each individual may respond differently after surgery. Please consult with your eye surgeon regarding the recovery process.

You will be given a Patient Information Card with important information about the Hydrus Microstent you received. You should keep the card in a safe place for future reference. This Patient Information Card should be shown to your current and future healthcare providers.

OTHER OPTIONS TO TREAT GLAUCOMA

There are alternatives to treat glaucoma other than the Hydrus Microstent. They include:

- Eye drops
- Glaucoma laser treatment
- Glaucoma surgeries without an implant to improve fluid drainage from the eye
- Other glaucoma devices implanted into Schlemm's canal or into another part of the eye to improve fluid drainage from the eye

- Glaucoma surgery in which a small piece of tissue is removed inside the eye to create a new channel for the fluid to drain from the eye
- Glaucoma drainage implants (e.g., shunts or fluid drainage tubes) to create a new channel for the fluid to drain from the eye)

BENEFITS OF THE HYDRUS MICROSTENT

The potential benefit of the Hydrus Microstent is the lowering of your eye pressure. This may aid in the management of your glaucoma.

The Hydrus Microstent pivotal clinical study included 369 patients who received the Hydrus Microstent at the same time as cataract surgery and 187 patients who had only cataract surgery. Patients were followed for 2 years after their surgery. For each 100 patients in the study, about 77 patients who received the Hydrus Microstent and cataract surgery experienced significant lowering of their eye pressure. Cataract removal itself may also lower eye pressure (but the pressure-lowering effects of cataract removal alone may be temporary). In this study, about 58 patients out of 100 who received only cataract surgery experienced the same result.

The inserter the surgeon would use to implant the Hydrus Microstent in your eye is different from the one used in this clinical study. The safety of the inserter that would be used to implant the microstent in your eye was evaluated in other clinical studies. Study results from those clinical studies showed the safety of the two inserters was similar.

The long-term effectiveness (after 2 years) of the Hydrus Microstent is still unknown.

RISKS OF THE HYDRUS MICROSTENT

In the same Hydrus Microstent clinical study, the risks of Hydrus Microstent were similar to the risks of having cataract surgery alone. In a small number of patients, other adverse events associated with Hydrus Microstent implantation were reported. There is a small risk that the microstent may not be implanted successfully or implanted in the proper position. The microstent may become blocked over time. You may experience inflammation in your eye that may need to be treated with eye drops containing steroids.

Although not reported frequently, there are other risks that may be related to use of the Hydrus Microstent. They include bleeding during surgery, persistent inflammation, tissue trauma, changes in your eye pressure that could affect your vision, the feeling that there is something in your eye, pain in your eye and glaucoma disease progression. Unplanned second surgeries may be needed to address these additional risks. Other general eye surgery risks include bleeding, infection, inflammation, increased eye pressure, vision changes, and swelling of the cornea. It is important that you discuss surgical risks with your eye surgeon.

After surgery, your surgeon will examine your eye and make sure your eye pressure is controlled. Further treatment with medicine such as eye drops or other glaucoma surgery may be recommended if your eye pressure is not controlled.

The safety and effectiveness of the Hydrus Microstent has not been established in patients with the following circumstances or conditions:

- Age 21 years or younger
- Eyes with significant prior trauma
- Eyes in which the front of the eye is abnormal
- Eyes with chronic inflammation
- Eyes with glaucoma associated with vascular disorders
- Eyes that already have an intraocular lens in the eye
- Eyes with uveitic glaucoma (glaucoma associated with inflammation inside your eye)
- Eyes with pseudoexfoliative glaucoma (glaucoma caused by a build-up of a white deposits in the eye) or pigmentary glaucoma (glaucoma caused by flaking of pigment 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 22 mmHg or greater 34 mmHg that are not using glaucoma medication
- Eyes with pressure greater than 31 mmHg that are using glaucoma medication
- Eyes in which cataract surgery complications occurred
- When Hydrus Microstent is implanted without cataract surgery

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

CONTRAINDICATIONS AND WARNINGS

The Hydrus Microstent should not be used in patients with the following types of glaucoma:

- Angle closure glaucoma: a type of glaucoma in which the iris is pushed forward narrowing the angle between the iris and the cornea. The closed angle would make the insertion of the Hydrus Microstent more difficult in this condition.
- Traumatic glaucoma: glaucoma caused by injury to the eye.
- Malignant glaucoma: glaucoma that usually occurs after intraocular surgery in patients with a history of angle closure glaucoma.

- Uveitic glaucoma: glaucoma resulting from eye inflammation of the middle layer of tissue in the eye wall (uvea).
- Neovascular glaucoma: a type of secondary glaucoma where the angle of the eye is closed by new blood vessels.

The Hydrus Microstent should not be used in patients with birth defects of the anterior chamber angle of the eye.

Warnings:

- The Hydrus Microstent consists of nickel-titanium (nitinol) alloy, which is generally considered safe. Individuals with allergic reactions to nickel may have an allergic response to this microstent, especially those with a history of metal allergies.
- Your eye doctor should periodically monitor your eye to assess the status of the microstent which may include taking photos.

SUMMARY OF CLINICAL STUDY

In the Hydrus Microstent pivotal clinical study, 558 patients with a diagnosis of mild to moderate POAG underwent cataract surgery, then were randomized to receive the Hydrus Microstent (Hydrus group) or receive no further treatment (control group). 369 patients received the Hydrus Microstent and 187 patients had cataract surgery only. Patients were followed for 2 years after their surgery to evaluate effectiveness of the Hydrus Microstent and to monitor ocular health.

For each 100 patients in the study, about 77 patients who received the Hydrus Microstent and cataract surgery experienced significant lowering of their eye pressure. About 58 patients out of 100 who received only cataract surgery experienced the same result.

The adverse events reported in the group who received the Hydrus Microstent were similar to the adverse events in the group who had cataract surgery alone. In a small number of patients, adverse events associated with Hydrus Microstent implantation were reported. These included the microstent not implanted successfully or not implanted in the proper position, blockage of the microstent and inflammation in the eye that was treated with eye drops containing steroids. Other adverse events related to use of the Hydrus Microstent that were reported less frequently included bleeding during surgery, persistent inflammation, tissue trauma, changes in eye pressure, a feeling of something in the eye, pain in the eye and glaucoma disease progression. In some instances, medicine such as eye drops or glaucoma surgeries were required.

EYE SYMPTOMS THAT MAY OCCUR WITH THE HYDRUS MICROSTENT

Patients in the Hydrus Microstent clinical study were asked to complete an eye symptom questionnaire during the course of the study. A small number of patients in both groups experienced worsening of some of these symptoms. Many patients had other eye conditions that may have contributed to their symptoms. 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 CLINICAL STUDY OF THE HYDRUS MICROSTENT

Symptoms Reported	Cataract Surgery and Hydrus Number of Patients Out of 100*	Cataract Surgery Alone Number of Patients Out of 100*
Eye irritation, burning	1	2
Eye pain	0	1
Excessive tearing	1	3
Droopy eyelids	0	1
Red eyes	0	2
Foreign body sensation (feeling that something is in your eye)	2	2
Skin sensitivity or irritation around the eye	1	2

Symptoms counted as worsening if they worsened 2 levels from the beginning of the study to "bothersome a moderate amount" or "bothersome a lot" throughout the 2 year study. *Rounded to the nearest whole number.

Symptoms reported as bothering the patient "a lot" or "a moderate amount" 2 years after surgery (even without worsening during the course of follow-up) are shown on **Table 2**.

TABLE 2: RATES OF SYMPTOMS REPORTED TO BOTHER THE PATIENT "A LOT" OR "A MODERATE AMOUNT" 2 YEARS AFTER SURGERY IN THE PIVOTAL CLINICAL STUDY OF THE HYDRUS MICROSTENT

Symptoms Reported	Cataract Surgery and Hydrus Number of Patients Out of 100*	Cataract Surgery Alone Number of Patients Out of 100*
Eye irritation, burning	5	7
Eye pain	1	2
Excessive tearing	4	4
Droopy eyelids	0	1
Red eyes	3	3
Foreign body sensation (feeling that something is in your eye)	3	7
Skin sensitivity or irritation around the eye	2	3

Symptoms are included if they were categorized as bothering the patient "a lot" or "a moderate amount" at 2 years after surgery, even if they didn't get worse during the study or were related to conditions that were present before the study started. *Rounded to the nearest whole number.

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