# PATIENT INFORMATION BROCHURE

iStent *inject*® Trabecular Micro-Bypass System

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



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**PATIENT INFORMATION BROCHURE**
**iStent *inject* Trabecular Micro-Bypass System**

This document has been provided to assist in your understanding of the iStent *inject* Trabecular Micro-Bypass System (referred to after this as iStent *inject*), which is one option for managing your glaucoma. Please read the entire brochure and discuss the benefits and risks with your eye care provider. Prior to undergoing any type of surgery, it is important to make sure your questions and concerns are fully addressed. The iStent *inject* procedure is performed at the same time of cataract surgery and results in 2 identical stent devices being implanted in the eye to help reduce your eye pressure.

## Open-Angle Glaucoma and Intraocular Pressure

Glaucoma is a disease that damages the optic nerve in the back of your eye and causes vision loss that worsens over time if not treated. There are different types of glaucoma. The most common type is called primary open-angle glaucoma. The iStent *inject* is specifically for patients with this particular type of glaucoma.

Your eyes produce a liquid (called aqueous humor) continuously in order to nourish the eye, which is essential for healthy eyes. With open-angle glaucoma the trabecular meshwork in your eye (the drainage structure) may look normal, but the fluid does not flow out properly and the pressure in your eye increases. This increased eye pressure can damage your optic nerve. Your eye doctor will measure the pressure in your eye. It is important to measure eye pressure because most people with glaucoma have no early symptoms or eye pain or there may be subtle changes, such as slight narrowing of your peripheral (side) vision. If left untreated, over time glaucoma may result in permanent vision loss and blindness.

## iStent *inject*

The iStent *inject* contains 2 tiny metal devices designed to stay in place inside the eye and


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create a drainage channel to increase the flow of fluid. **Figure 1** below shows how tiny the stents are by comparing those to a U.S. penny. These 2 stents are preloaded into a custom injector, which is the instrument your surgeon uses to implant the stents in your eye. During cataract surgery, the 2 stents will be placed closely together to help reduce eye pressure.

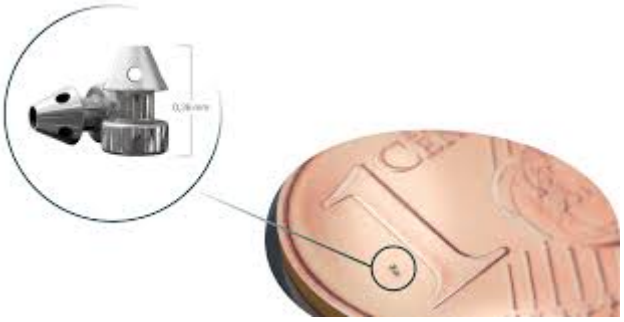

**Figure 1 – iStent *inject* compared to a penny**

When implanted in the eye in the iStent *inject* can help lower your eye pressure by providing a channel for the eye fluid to move out of the front chamber of the eye. Less fluid in the chamber means lower pressure. **Figure 2** shows what the iStent *inject* looks like once it is implanted in the eye.

**Arrows show fluid drainage pathway**

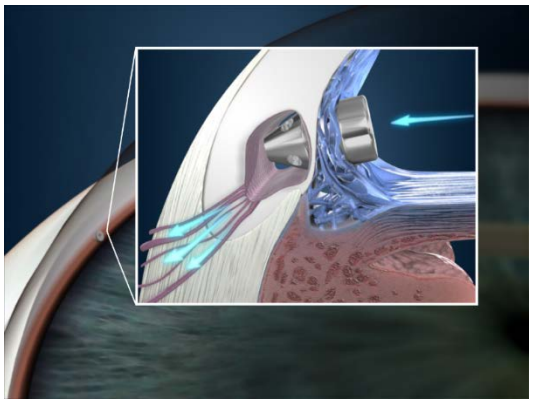

**Figure 2 – iStent *inject* implanted in the eye**

### Cataract Surgery with iStent *inject*

A cataract is a clouding of the lens in the eye that affects vision. Most cataracts are related to the process of aging. Symptoms of cataracts may include cloudy or blurry vision, colors that seem faded, difficulty with glare (such as in direct sunlight or with oncoming headlights) and

more frequent changes in glasses or contact lens prescriptions. Cataract surgery involves the removal of the cloudy natural lens and replacement with an artificial (intraocular) lens (also called an IOL). When you have cataract surgery along with the iStent *inject* as part of a single procedure, the 2 stents are implanted in your eye immediately after your cataract is removed and an IOL is implanted. Your eye surgeon will use the same surgical incision that was used to remove your cataract to insert the iStent *inject*.

**Before Surgery**

Before surgery your doctor will examine your eye, take measurements of your eye and eye pressure, and determine which type of intraocular lens (IOL) is best for you. Depending on which medications you are taking, you may be asked to stop taking them a few days before surgery or you may be asked to start new medications. Your doctor may have additional recommendations for you. Before surgery make sure you ask questions about anything you don't understand.

**Surgery Day**

On the day of surgery, you will be given eye drops and possibly medicine to help you feel more relaxed. You will also be given drugs to numb the eye so that you do not feel pain during the procedure. Your surgeon will perform cataract surgery using a microscope that shows a magnified view of your eye. The natural lens is enclosed in a bag-like structure called the capsule. The capsule is located behind the iris, which is the colored part of your eye. Your surgeon will make a small incision in the outer surface of the eye and remove your cataract. Then an IOL will be implanted into the capsule to replace your natural lens. Once implanted, the IOL performs just like your natural lens to restore clear vision. Immediately after the cataract portion of the surgery is completed, your surgeon will use the same incision to enter the eye with the iStent *inject* injector instrument and the 2 stents will be implanted.

After the procedure, your eye surgeon will usually place a shield over your eye after surgery to protect your eye. You will spend a short time in the outpatient recovery area


 

and afterwards you will be able to go home to recover. You will not be allowed to drive home so you will need to plan to have someone drive you home. Your eye surgeon will provide you with specific instructions after surgery.

**After Surgery**

You will be given eye drops to help your eye heal and prevent infection and your doctor will give you specific instructions for when to use your eye drops. Your eye doctor will examine you after surgery (usually the day after surgery) and check your eye pressure, which may change during the first several days after surgery. Be sure to talk with your doctor to make sure you understand the recovery process and postoperative instructions.

Your eye doctor should give you a Patient Identification card that contains important information about your iStent *inject*. Please should keep this card in a safe place and show it to your current and future healthcare providers.

Your eye doctor will monitor you after surgery to make sure your eye pressure is controlled. If needed, your doctor will recommend additional therapy, including appropriate medication or other treatment, to control your eye pressure.

**Other Treatment Options**

The following treatments options are alternatives to the iStent *inject*:

- Prescription eye medication
- Glaucoma laser treatment
- Trabecular bypass surgery (insertion of a stent to improve drainage of fluid by going around the blocked fluid drainage channels)
- Stent implantation into the suprachoroidal space, which is an alternate exit pathway deeper in the eye for fluid drainage
- Glaucoma surgeries to unblock fluid drainage channels, such as trabectome, canaloplasty, viscocanalostomy, trabeculotomy or filtration surgery
- Implantation of shunts or fluid drainage tubes to create an opening that allows


 

fluid to drain out of the eye

**iStent *inject* Potential Benefits**

The potential benefit of the iStent *inject* is the lowering of eye pressure, which may assist in the management of your glaucoma. In a clinical study conducted in the United States, 380 patients received the iStent *inject* stents at the same time as cataract surgery and 118 patients had cataract surgery alone with no stents. These study patients were monitored for 2 years after their surgery. For each 100 patients in the study, approximately 76 patients who received the iStent *inject* plus cataract surgery experienced significant lowering of their eye pressure, whereas approximately 62 patients who had cataract surgery only experienced similar results.

**iStent *inject* Potential Risks**

The risks of iStent *inject* with cataract surgery are similar to the risks of having cataract surgery alone. There are, however, some additional risks associated with iStent *inject* implantation that were reported in a small number of patients. There is a small risk that the iStent *inject* stents may not be implanted successfully or implanted in the planned position. Stents may become blocked over time and you may need to have a second procedure to clear the blockage. Although uncommon, there are other risks that may be related to use of the iStent *inject*. These risks may include bleeding during surgery, inflammation, tissue trauma, changes in eye pressure that could affect vision, the feeling that there is something in your eye, eye pain, and progression of your glaucoma disease. General risks of eye surgery include reactions to medicines, bleeding, infection, inflammation, vision changes, increased eye pressure, and swelling of the cornea.

Medications or unplanned second surgeries may be needed to address these additional risks. Please discuss all risks and benefits with your eye surgeon before your surgery.

During the clinical trial, only certain patients were able participate in the study. Because of this it is important to note that the safety and effectiveness of the iStent


 

*inject* has not been established in children and 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 associated with vascular disorders (disorders related to blood vessels)
- Eyes with pseudoexfoliative glaucoma (glaucoma caused by a build-up of deposits in the eye)
- Eyes with pigmentary glaucoma (glaucoma caused by flaking of iris pigment. (Note that the iris is the colored portion of your eye)
- Eyes with secondary open-angle glaucoma
- Eyes with glaucoma that have had prior cataract surgery
- Eyes with uveitic glaucoma (glaucoma associated with inflammation in your eye)
- Eyes that have had prior surgery to treat glaucoma. Note, selective glaucoma laser treatment more than 3 months ago is acceptable.
- Eyes with pressure greater than 24 mmHg that are using glaucoma medication
- Eyes with pressure less than 21 mmHg or greater than 36 mmHg that are not using glaucoma medication
- Eyes in which cataract surgery complications occurred
- When iStent *inject* stents are implanted without cataract surgery

The safety and effectiveness of use of more than or less than two iStent *inject* stents per eye has not been established. iStent *inject* has not been shown to be an alternative to treatment of glaucoma with medicine.

The following conditions may prohibit your doctor from having a sufficient view of your eye that is required for safe and successful stent implantation: corneal haze or opacity (cloudiness in the front part of your eye), or any other conditions that may inhibit the view in the intended


 

implant location.

Your doctor should perform an eye exam prior to surgery to exclude congenital anomalies (birth defects) of the area where the stent will be placed, including peripheral anterior synechiae (PAS; tiny adhesions around the colored area of your eye), rubeosis (abnormal blood vessels), and any other abnormalities that could lead to improper placement of the stent and pose a hazard.

Patients with peripheral iridotomies of the iris (surgery of the colored area of your eye) are at risk of stent dislocation within the eye, which can cause other problems.

The iStent *inject* is intended for implantation during cataract surgery, which may impact corneal (transparent layer in front portion of your eye) health. Therefore, caution is advised in eyes with evidence of corneal problems or with risk factors for corneal problems following cataract surgery (e.g., advanced age or severe cataract).

After the surgery, your doctor will give you an implant card with the appropriate information filled in, and you should keep the card in a safe place, e.g., your wallet or purse, for future reference. The implant card contains important information related to the iStent *inject* and that the card should be shown to your current and future health care providers. The implant card also identifies the iStent *inject* stent as "MR Conditional" (**M**agnetic **R**esonance). If you need to undergo an MRI (**M**agnetic **R**esonance **I**maging is a noninvasive test that uses magnets), you should let your doctor know that you have an iStent *inject* stent implanted in your eye, and show the doctor your implant card.

Your doctor will monitor your eye pressure after surgery. If your eye pressure is not adequately maintained after surgery, your doctor will consider medication or other treatment to reduce your eye pressure.

The effectiveness of the iStent *inject* system has been demonstrated only in patients with mild


 

to moderate open-angle glaucoma who had the stent implanted during cataract surgery.

The stent is made of implant grade titanium with a heparin (blood thinning) coating. The total amount of heparin is estimated to be less than 0.9 microgram per stent, or approximately 0.01 to 0.02 units.

**Is the iStent *inject* right for me?**

iStent *inject* may be a good option if you have glaucoma that is not severe, and you are planning to have surgery to remove your cataract. 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 iStent *inject*, or if there is a condition that may prevent your eye surgeon from seeing where iStent *inject* will be implanted.

**When should the iStent *inject* not be used?**

The iStent *inject* Trabecular Micro-Bypass System should not be used in patients who have one of the following conditions: angle closure glaucoma (quick or sudden increase in IOP); traumatic, malignant, uveitic (inflammation of the eye tissue (uvea), or neovascular (related to the iris (colored part of eye) and/or anterior chamber) glaucoma or noticeable birth irregularities of the anterior chamber (AC) angle; or retrobulbar (Orbital) tumor, thyroid eye disease, Sturge-Weber Syndrome (neurological/nerve disorder marked by a distinctive port-wine stain on the forehead, scalp or around the eye) or any other type of condition that may cause elevated pressure in the veins of the eye (episcleral venous pressure).

**iStent *inject* Study**

In the United States, a clinical study looked at the safety and effectiveness of iStent *inject* in lowering eye pressure in patients with primary open angle glaucoma who were undergoing cataract surgery. In this study, 380 patients received iStent *inject* at the same time as cataract surgery, and 118 patients had cataract surgery only. Patients with iStent *inject* and cataract surgery achieved a significant lowering of their eye pressure more often than patients who only had cataract surgery. For each 100 patients in the study, approximately


 

76 patients who received the iStent *inject* plus cataract surgery experienced significant lowering of their eye pressure, whereas approximately 62 patients who had cataract surgery only experienced similar results. This lowered eye pressure lasted through the 2 year-long study. The overall safety of the patients who had iStent *inject* and cataract surgery patients was similar through the 2 year-long study compared to the overall safety of the patients who had cataract surgery only.

**Eye Symptoms Reported by Patients after Surgery**

Patients in the iStent *inject* clinical study were asked about eye symptoms they experienced during 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 iStent *inject* stents 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 Eye Symptoms**
**2 Years after Surgery in the U.S. Clinical Study of iStent *inject***

| | **Cataract Surgery and iStent *inject***<br><br>***Number of Patients Out of 100*** | **Cataract Surgery Alone**<br><br>***Number of Patients Out of 100*** |
|---|---|---|
| Eyes that are sensitive to light | 6 | 6 |
| Eyes that feel gritty | 2 | 2 |
| Eyes that feel painful or sore | 2 | 1 |
| Blurry vision | 2 | 2 |
| Poor vision | 1 | 2 |
| Difficulty with reading | 3 | 3 |
| Difficulty with driving at night | 1 | 7 |
| Difficulty working with a computer or bank machine (ATM) | 3 | 1 |
| Difficulty watching TV | 1 | 1 |
| Eyes felt uncomfortable in windy conditions | 3 | 2 |
| Eyes felt uncomfortable in places or areas with low humidity (very dry) | 2 | 2 |
| Eye felt uncomfortable in areas that are air conditioned | 2 | 1 |

Ocular symptoms were considered as "worsening" if they were rated as being two grades worse than at the beginning of the study

**Table 2** shows eye symptoms that study patients reported experiencing "most of the time" or "all of the time" 2 years after the surgery, even if their symptoms did not worsen during the study.

**Table 2: Rates of Eye Symptoms Occurring "most of the time" or "all of the time" 2 Years after Surgery in the U.S. Clinical Study of iStent *inject***

| | **Cataract Surgery and iStent *inject*** ***Number of Patients Out of 100*** | **Cataract Surgery Alone** ***Number of Patients Out of 100*** |
|---|---|---|
| Eyes that are sensitive to light | 10 | 12 |
| Eyes that feel gritty | 2 | 3 |
| Eyes that feel painful or sore | 1 | 1 |
| Blurry vision | 4 | 6 |
| Poor vision | 3 | 3 |
| Difficulty with reading | 6 | 6 |
| Difficulty with driving at night | 9 | 11 |
| Difficulty working with a computer or bank machine (ATM) | 5 | 3 |
| Difficulty watching TV | 1 | 2 |
| Eyes felt uncomfortable in windy conditions | 4 | 5 |
| Eyes felt uncomfortable in places or areas with low humidity (very dry) | 5 | 3 |
| Eye felt uncomfortable in areas that are air conditioned | 3 | 1 |

Symptoms were included if they were reported at 2 years as occurring "most of the time" or "all of the time", even if the symptoms did not worsen during the study or were related to conditions that were present before the study started.

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