

PATIENT INFORMATION BROCHURE

iStent infinite® Trabecular Micro-Bypass System



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

This document has been provided to assist in your understanding of the iStent infinite® Trabecular Micro-Bypass System, Model iS3 (referred to after this as iStent infinite), 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. During the iStent infinite procedure, 3 identical stent devices are 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 open-angle glaucoma. The iStent infinite is specifically for patients with this particular type of glaucoma that has not been controlled, despite prior surgical therapy.

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 infinite

The effectiveness of the iStent infinite has been demonstrated in patients with primary open-angle glaucoma where previous surgical treatment has failed.

The iStent infinite contains 3 tiny metal devices (stents) designed to stay in place inside the eye and 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. When the stents are implanted in your eye, they are not visible to you or others without special eye examination equipment. These 3 stents are

preloaded into a custom injector, which is the instrument your surgeon uses to implant the stents in your eye. During surgery, the 3 stents will be placed closely together to help reduce eye pressure.

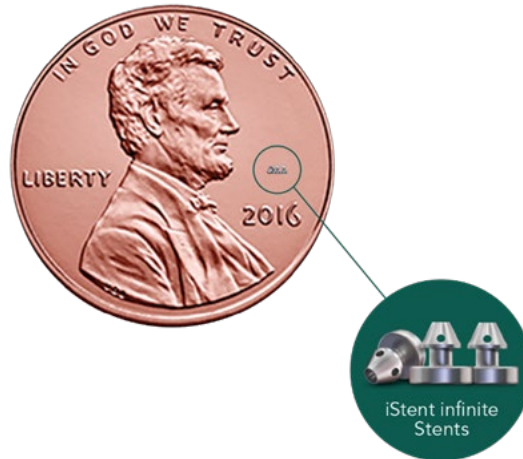


Figure 1 – iStent infinite compared to a penny

When implanted in the eye, the iStent infinite 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 infinite looks like once it is implanted in the eye.

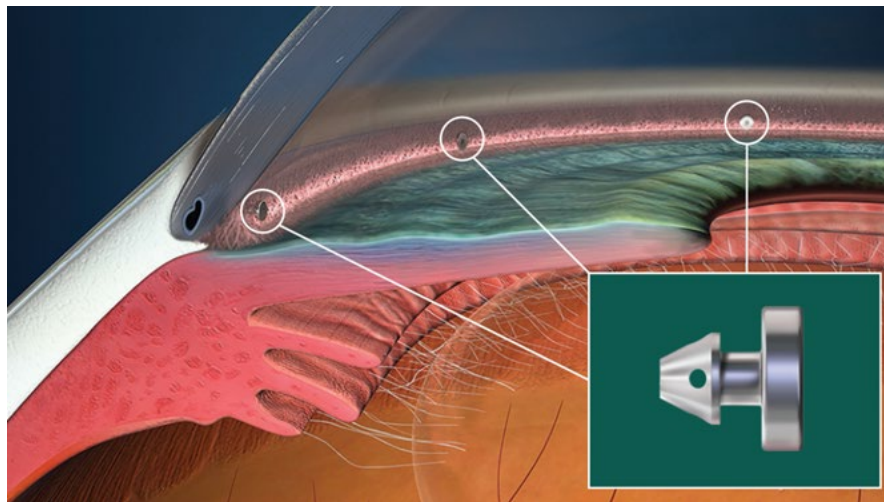


Figure 2 – iStent infinite implanted in the eye

Surgery with iStent infinite

During the iStent infinite procedure, 3 identical stent devices are implanted in the eye.

Before Surgery

Before surgery your doctor will examine your eye, and take measurements of your eye and eye pressure. 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 do not 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 the iStent infinite procedure using a microscope that shows a magnified view of your eye. Your surgeon will make a small incision in the outer surface of the eye to enter the eye with the iStent infinite injector instrument that contains the 3 stents, and the 3 stents will be implanted.

After the procedure, your eye surgeon will usually place a shield over your eye at the end of 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 infinite. Please 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 options are surgical alternatives to the iStent infinite in patients with uncontrolled glaucoma despite prior surgical therapy, depending on your condition:

- Stent implantation into the subconjunctival space, which is an alternate exit pathway for fluid drainage
- Glaucoma surgeries to unblock fluid drainage channels, such as Trabectome®, goniotomy, canaloplasty, viscocanalostomy, or trabeculotomy
- Implantation of shunts or fluid drainage tubes or other filtration procedures (e.g, trabeculectomy) to create a new drainage channel that allows fluid to drain out of the eye
- Cilioablative procedures (such as cryotherapy or cyclodiode therapy) to decrease the production of eye fluid
- Revision of prior glaucoma surgery

iStent infinite Potential Benefits

The potential benefit of the iStent infinite is the lowering of eye pressure, which may assist in the management of your glaucoma. In a clinical study conducted in the United States, 61 study patients received the iStent infinite. Study patients were monitored for 1 year after their surgery. At 1 year, approximately three-quarters of patients experienced lowering of 20% or more of their eye pressure compared to their eye pressure before the surgery while using the same or fewer types of eye drops.

iStent infinite Potential Risks

General risks of eye surgery may also occur with iStent infinite implantation and include reactions to medicines, bleeding, infection, inflammation, vision changes, increased eye pressure, and swelling of the cornea. There are, however, some additional risks associated with iStent infinite implantation that were reported in a small number of patients. There is a small risk that the iStent infinite stents may not be implanted successfully or implanted in the planned position. Stents may become blocked over time and you may need to have medications or a second procedure to clear the blockage. Although uncommon, there are other risks that may be related to use of the iStent infinite. These risks may include bleeding during surgery, inflammation, tissue trauma, changes in eye pressure that could affect vision, and progression of your glaucoma disease. Medications or additional surgeries may be needed to address these risks. Please discuss all risks and benefits with your eye surgeon before your surgery.

Is the iStent infinite right for me?

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 infinite has not been established in children and adult 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 secondary open-angle glaucoma
- Eyes that have had prior argon laser trabeculoplasty (ALT) to treat glaucoma
- Eyes that have had selective laser trabeculoplasty (SLT), any other glaucoma surgery or any other intraocular surgery within 90 days before iStent infinite implantation
- Eyes that have not had prior glaucoma filtering or cilioablative surgery
- Eyes with pressure less than 20 mmHg
- Eyes with pressure greater than 35 mmHg

iStent infinite has not been shown to be an alternative to the primary treatment of glaucoma with medicine or lasers.

Because the clinical trial was not designed to study separate groups of eyes that had or had not undergone prior cataract surgery, the safety and effectiveness of the iStent infinite has not been fully studied in eyes that have not undergone prior cataract surgery.

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.

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 infinite and that the card should be shown to your current and future health care providers. The implant card also identifies the iStent infinite 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 infinite 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 stent is made of implant grade titanium with a heparin (blood thinning) coating. The total miniscule amount of heparin is estimated to be less than 0.9 microgram per stent.

iStent infinite may be a good option if you have glaucoma that has not been controlled despite previous surgery. 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 infinite, or if there is a condition that may prevent your eye surgeon from seeing where iStent infinite will be implanted.

When should the iStent infinite not be used?

The iStent infinite Trabecular Micro-Bypass System should not be used in patients who have one of the following conditions: angle-closure glaucoma (a type of glaucoma in which the iris is pushed forward closing the drainage angle between the iris and the cornea); traumatic glaucoma (glaucoma caused by injury); uveitic glaucoma (glaucoma associated with inflammation in your eye); neovascular glaucoma (a type of glaucoma where the angle is closed by abnormal formation of new blood vessels; congenital irregularities of the drainage angle; glaucoma related to tumors; 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 infinite Study

In the United States, a clinical study looked at the safety and effectiveness of iStent infinite in lowering eye pressure in patients with open-angle glaucoma not controlled by prior glaucoma surgeries. In this study, 61 patients received the iStent infinite and were monitored for 1 year after their surgery. At 1 year, approximately three-quarters of patients experienced lowering of 20% or more of their eye pressure compared to their eye pressure before the surgery while using the same or fewer types of eye drops. In a small number of patients, adverse events associated with iStent infinite implantation were reported. These included the stents not implanted in the proper position, blockage of the stent, and inflammation in the eye that either resolved without treatment or was treated with anti-inflammatory eye drops. Other adverse events related to use of the iStent infinite

that were reported less frequently included bleeding during surgery and glaucoma disease progression. In some instances, medicine such as eye drops or glaucoma surgeries were required.



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