PATIENT INFORMATION LEAFLET

iStent *inject*® Trabecular Micro-Bypass System,
Model G2-M-IS

Device description

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.

Intended Purpose of the iStent *inject*

The iStent *inject* procedure is intended to treat adult patients diagnosed with mild to moderate open-angle glaucoma (POA). The procedure may be performed with or without cataract surgery. Two identical stent devices are implanted in the eye to help reduce your eye pressure.

Expected Lifetime of the device

The iStent *inject* is designed to last throughout your lifetime.

Is the iStent *inject* right for me?

You have been diagnosed with glaucoma which is a disease that damages the optic nerve in the back of the eye and can cause vision loss. There are different kinds of glaucoma. The most common type is called primary open angle glaucoma. The iStent *inject* may be a good option if you have this kind of glaucoma and/or if you are planning to have surgery to remove your cataract.

A cataract is a clouding of the lens in the eye that affects vision. If you have cataract surgery along with the iStent *inject* as part of a single procedure, 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*.

iStent *inject*

The iStent *inject* contains 2 tiny metal devices 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. The stents are made of implant grade titanium and coated with a very thin layer of heparin coating. The total amount of heparin is very minute, i.e. estimated to be less than 0.9 microgram per stent, or approximately 0.01 to 0.02 units.

These 2 stents are preloaded into a custom injector, which is the instrument your surgeon uses to implant the stents in your eye. During implant 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.

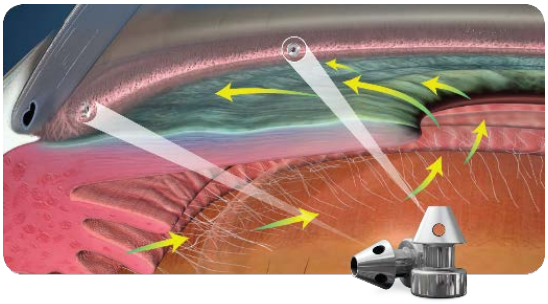

Figure 2 – iStent *inject* implanted in the eye

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 (if applicable). 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 the 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. If you are also having cataract surgery, the cataract will be removed, and 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.

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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 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" (Magnetic Resonance). If you need to undergo an MRI (Magnetic Resonance Imaging 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 and show it to your current and future healthcare providers.

Potential Undesirable Side Effects

The following side effects could possibly result from use of this product:

- Significant Blood in front of the eye (hyphema)
- Significant iris damage
- Significant loss of best corrected visual acuity (BCVA)
- Stent dislocation or malposition
- Stent obstruction
- Cataract formation or progression in eyes that have the natural lens intact.

Residual Risks

Medications or second surgeries may be needed to address the potential side effects listed above. Further, due to the progressive nature of glaucoma regardless of treatment with this product, you may need medications or second surgeries, even after you have been treated with this product.

Symptoms that could indicate that the device is malfunctioning

If you experience any unusual symptoms, e.g. eye pain, vision loss, contact your eye doctor.

Precautions and preventative measures

Regular appointments with your eye doctor are recommended so that they can 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.

Discuss an appropriate follow-up schedule with your eye doctor based upon your medical history.

Any serious incident that occurs in relation to the stent device should be reported to the manufacturer using email medicalsafety@glaukos.com and to the Therapeutic Goods Administration. The address of the Therapeutic Goods Administration's website is: https://www.tga.gov.au/

MRI INFORMATION

Static magnetic field of 3-Tesla or less:
Non-clinical testing has demonstrated that the iStent *inject* Trabecular Micro-Bypass Stent, Model G2-M-IS is MR Conditional.

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field: 3T or less
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the iStent *inject* Trabecular Micro-Bypass Stent, Model G2-M-IS is not expected to produce a clinically significant temperature rise after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends less than 15 mm from the device when imaged with a gradient echo pulse sequence and a 3T MRI system.

Static magnetic field of 7-Tesla, ONLY:
Non-clinical testing demonstrated that the iStent *inject* Trabecular Micro-Bypass Stent, Model G2-M-IS is MR Conditional.

A patient with this device can be safely scanned immediately after implantation in an MR system meeting the following conditions:

- Static magnetic field of 7T, ONLY
- Maximum spatial gradient magnetic field of 10,000-gauss/cm (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence)
- First Level Controlled Operating Mode of operation for the MR system
- Use of a transmit/receive RF head coil, ONLY

MRI-Related Heating
In non-clinical testing, the device produced a temperature rise of 0.4°C during MRI performed for 15-minutes of scanning (i.e., per pulse sequence) in a 7-Tesla/298-MHz MR system (Philips Acheiva, Philips

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Healthcare, Cleveland, OH) using at transmit/receive RF head coil.
MR system reported, whole body averaged: SAR < 1-W/kg.

Artifact Information
In non-clinical testing, the image artifact caused by the device extends approximately 23-mm from this device when imaged using a gradient echo pulse sequence and a 7T MR system.

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