

iStent inject® W Trabecular Micro-Bypass System INSTRUCTIONS FOR USEP-000584
Rev 3/07/24**DEVICE DESCRIPTION**

| Catalogue # | Description |
|-------------|---|
| IS2 | Glaukos® iStent inject® W System Model IS2 with Two (2) G2-W trabecular heparin coated Trabecular Micro-Bypass Stents preloaded in one injector |

WARNINGS/PRECAUTIONS

- For prescription use only.
- Intended users are trained ophthalmologists only.
- This device has not been studied in patients with uveitic glaucoma.
- Do not use the device if the Tyvek® lid has been opened or the packaging appears damaged. In such cases, the sterility of the device may be compromised.
- Due to the nature of certain injector components (i.e. the insertion sleeve and trocar), care should be exercised to grasp the injector body.
- Dispose of device in a sharps container.
- iStent inject W MR-Conditional: see MR Information below.
- Physician training is required prior use of the iStent inject System.
- Do not re-use the stents(s) or injector, as this may result in infection and/or intraocular inflammation, as well as occurrence of potential postoperative adverse events as shown below under "Potential Complications".
- To our knowledge, no known compatibility issues with the iStent inject W and other intraoperative devices (e.g., viscoelastics) or glaucoma medications.
- Unused product & packaging may be disposed of in accordance with facility procedures: implanted medical devices and contaminated products must be disposed of as medical waste.
- The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. If intraocular pressure is not adequately maintained after surgery, the surgeon should consider an appropriate treatment regimen to reduce intraocular pressure.
- Patients should be informed that placement of the stents, without consideration of cataract surgery in phakic patients can enhance the risk of cataract formation.

POTENTIAL COMPLICATIONS

Intraoperative or postoperative adverse events may be device-related or inner contents of the blister tray are sterile. Two stents are already assembled onto the single-use injector. The blister tray lid is labeled with the required product identification information. A lot number and serial number are provided on the labeling. The iStent inject W System is sterilized by gamma irradiation.

The expiration date on the device package (tray lid) is the sterility expiration date. In addition, there is a sterility expiration date that is clearly indicated on the outside of the unit/center. Sterility is assured if the tray seal is not broken, punctured or damaged until the expiration date. This device should not be used past the indicated sterility expiration date.

INDICATIONS FOR USE

The iStent inject W is intended to reduce intraocular pressure safely and effectively in adult patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma.

The device is safe and effective when implanted in combination with or without cataract surgery in those subjects who require intraocular pressure reduction and/or would benefit from glaucoma medication reduction.

The device may also be implanted in patients who continue to have elevated intraocular pressure despite prior treatment with glaucoma medications and/or conventional glaucoma surgery.

CONTRAINdicATIONS

The iStent inject W system is contraindicated under the following circumstances or conditions:

- o In eyes with primary angle closure glaucoma, or secondary angle-closure glaucoma, including neoplastic glaucoma, because the device would not be expected to work in such situations

o In patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure

INSTRUCTIONS FOR USE

1) Remove the Stent Delivery Button Lock from the injector.

2) Make a corneal incision of adequate length to allow entry of the introducer tip of the injector into the anterior chamber.

Recall the iStent incision location is the temporal peripheral cornea for either eye. Optimal viscoelastic (cohesive) should be used to form the anterior chamber, as necessary. Deepen the anterior chamber by injecting with viscoelastic as needed, being careful not to overinflate.

3) The iStent inject W injector steps are as follows: With the gonioscopium removed from the cornea, insert the injector Introducer Tip through the clear corneal incision into the anterior chamber. Once the Introducer Tip has been inserted through the corneal incision, the Introducer Tip then retracts exposing the Insertion Tube and Trocar. Care should be taken to avoid contact with the IOL, iris or cornea.

4) Place the gonioscopium on the cornea and position the patient and surgical microscope as needed to visualize the trabecular meshwork through the gonioscopium on the nasal side of the eye.

5) Advance the Insertion Tube containing the trocar towards the TM (just above the scleral spur) and penetrate the trocar tip through the center of the TM. The trocar is used to not only penetrate the TM, but will remain in the tissue to act as an axial guide for the stent as the stent is deployed across the trocar tip through to Schlemm's canal.

MR INFORMATION**MR**

The static magnetic field of 3-Tesla or less:

Non-clinical testing has demonstrated that the iStent inject W Trabecular Micro-Bypass Stent, Model IS2 is MR Conditional.

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

• Static magnetic field of 3T or less

• Maximum spatial gradient magnetic field of 4,000 gauss/cm (extrapolated) or less

• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4/W/kg First Level Controlled Operating Mode)

MR-Conditional 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 Achieva, Cleveland, OH) using a transit/receive RF head coil.

The system reported, whole body averaged: SAR < 1-W/kg.

Artificial 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.

Static magnetic field of 7-Tesla, ONLY:

Non-clinical testing demonstrated that the iStent inject W Trabecular Micro-Bypass Stent, Model IS2 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 transit/receive RF head coil, ONLY

MRI-Related Heating

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