iStent *inject*® W Trabecular Micro-Bypass System
INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

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

The iStent *inject*® W System contains two intraocular stents that are manufactured from implant grade titanium (Ti6Al4V ELI) and are coated with stearalkonium heparin (note: the heparin is from a porcine source). The stent has a single piece design, is approximately 360 microns in height and 360 microns in diameter. The injector has been designed by Glaukos Corporation to implant two Model G2-W stents into Schlemm's canal, which creates a patent opening in the trabecular meshwork and re-establishes normal physiological outflow.

HOW SUPPLIED

Each iStent *inject* W System is provided sterile in a blister tray (only the 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. The iStent *inject* W System is individually serialized and the injector is labeled with a lot number 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 carton. 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.

INTENDED USE

Intended to reduce intraocular pressure safely and effectively in patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma, or pigmentary glaucoma.

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 iStent *inject* W can deliver two (2) stents on a single pass, through a single incision. The implant is designed to stent open a passage through the trabecular meshwork to allow for an increase in the facility of outflow and a subsequent reduction in intraocular pressure.

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.

INTENDED PATIENT POPULATION

Adult patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma, or pigmentary glaucoma.

CONTRAINDICATIONS

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

- In eyes with primary angle closure glaucoma, or secondary angle-closure glaucoma, including neovascular glaucoma because the device would not be expected to work in such situations.
- In patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure.

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1) Make a corneal incision. Stabilize the anterior chamber to ensure it remains inflated.
2) Place a commercially available gonioscope on the cornea and reposition the surgical microscope as needed to visualize the trabecular meshwork, through the gonioprism, on the nasal side of the eye.
3) Enter the eye with the iStent *inject* W.
4) Slide the retraction (back) button to draw back the insertion sleeve and expose the insertion tube and trocar.
5) Advance the trocar tip to the center of the trabecular meshwork.
6) Press the trigger (front) button to inject the stent through the trabecular meshwork and into Schlemm's Canal.
7) Look through the slot in the insertion tube and verify the stent is securely in place.
8) While remaining in the eye, relocate the tip of the injector for implantation of the second stent; repeat steps 5 through 7.
9) Remove the injector from the eye.
10) Irrigate the anterior chamber with balanced salt solution (BSS) through the corneal wound to remove all viscoelastic. Press down on the posterior edge of the incision as needed to facilitate complete removal of viscoelastic.
11) Inflate the anterior chamber with saline solution as needed to achieve normal physiologic pressure.
12) Ensure that the corneal incision is sealed.

Retrieval of an Implanted Stent

1) Prep the patient as one would for stent implantation surgery.
2) Re-open the eye at the preferred location in order to reach the stent. A clear corneal incision measuring approximately 1.5mm in length is recommended.
3) Use cohesive viscoelastic to inflate the anterior chamber to create access to the stent's location,

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move the stent away from a delicate structure if loose, and/or protect intraocular tissues.

4) Use a commercially available gonioscope if needed to visualize the location of the stent in the anterior chamber.
5) Insert a micro forceps device through the corneal incision and grasp the stent in a convenient and secure manner before removing the stent from the anterior chamber.
6) Irrigate the anterior chamber with balanced salt solution (BSS) through the corneal wound to remove all viscoelastic. Press down on the posterior edge of the incision as needed to facilitate complete removal of viscoelastic. Repeat as needed until all viscoelastic has been removed.
7) Inflate the anterior chamber with saline solution as needed to achieve normal physiologic pressure.
8) Ensure that the corneal incision is sealed.

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 sharpness 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 is MR-Conditional; see MRI Information below.
- Physician training is required prior to use of the iStent *inject* W System.
- Do not re-use the stent(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."
- There are 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 concomitant cataract surgery in phakic patients can enhance the formation or progression of cataract.

POTENTIAL COMPLICATIONS

Intraoperative or postoperative adverse events may be device-related or non-device related.

Potential intraoperative events are as follows:

- Choroidal hemorrhage or effusion
- Crystalline lens touched by injector
- Posterior capsular bag rupture, in case of combined cataract surgery
- Prolonged anterior chamber collapse
- Significant corneal injury
- Significant damage to trabecular meshwork
- Significant hyphema
- Significant iris damage
- Vitreous loss or vitrectomy, in case of combined cataract surgery
- Stent malposition or loose stent inside eye requiring reacquisition

Potential postoperative events are as follows:

- Choroidal complication (massive hemorrhage or effusion)
- Chronic hypotony
- Clinically significant cystoid macular edema
- Endophthalmitis
- Flat anterior chamber
- Significant loss of best corrected visual acuity (BCVA)
- Intraocular inflammation (non-preexisting)
- IOL dislocation (in pseudophakic eyes)
- IOP increase requiring management with oral or intravenous medications or with surgical intervention
- Pupillary block
- Retinal complications (dialysis, flap tears, detachment, or proliferative vitreoretinopathy)
- Secondary surgical intervention including, but not limited to, the following :
  - Trabeculectomy
  - IOL repositioning or removal
  - Stent repositioning or removal
- Significant corneal complications including edema, opacification, decompensation
- Significant damage to the trabecular meshwork
- Significant hyphema
- Significant iris damage
- Stent dislocation or malposition
- Stent obstruction

STORAGE REQUIREMENTS

The device should be stored at room temperature (15-30°C).

MRI INFORMATION

Static magnetic field of 3-Tesla or less:
Non-clinical testing has demonstrated that the iStent *inject* W Trabecular Micro-Bypass Stent, Model G2-W 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)

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Under the scan conditions defined above, the iStent *inject* W Trabecular Micro-Bypass Stent, Model G2-W 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* W Trabecular Micro-Bypass Stent, Model G2-W 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 Achieva, Philips 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.

LABELING

The following symbols are used on the device packaging.

Symbol	*Definition*
REF	Catalogue/Model Number
SN	Serial Number (for the stent)
LOT	Lot Number
	Do not reuse
yyyy-mm-dd	Use By (year-month-day)
	Do not use if package is damaged
STERILE R	Sterilized by Gamma Irradiation
15 °C 30 °C	Temperature Storage Requirements
CE	CE Marking
MR	MR Conditional
Rx Only	For Prescription use only
	Consult Instructions For Use
	Manufacturer
EC REP	Authorized representative in the European Community
MD	Medical Device
BIO	Contains biological Material of animal origin
31	Implant Date
	Health care centre or doctor
	Patient name
	Patient Information website
#	Patient number
	Importer
UDI	Unique Device Identifier
QTY	Quantity
	Single *sterile* barrier system with protective packaging outside

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	Date of manufacture

EC REP

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The Summary of Safety and Clinical Performance of the G2-W with UDI-DI 00853704002401 can be found on https://ec.europa.eu/tools/eudamed.

If during the use of this device or as a result of its use, a serious incident has occurred, please report it immediately to Glaukos at MedicalSafety@glaukos.com. Upon receipt, Glaukos will assess the event for reportability and report the event to the national Competent Authority as required.