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

DEVICE DESCRIPTION

Catalogue #	Description
iS2	iStent *inject*® W System with two (2) G2-W Stearalkonium Heparin coated Trabecular Micro-Bypass Stents preloaded in one injector

The iStent *inject*® W System (Model iS2) contains two wide flange intraocular stents that are manufactured from titanium and coated with Stearalkonium Heparin. Each 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 through a single incision into Schlemm's canal.

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.

Materials to which patients can be exposed: 100% implant-grade titanium alloy (Ti6Al4V ELI) and 100% Stearalkonium Heparin (biocompatible stent coating). Note: the heparin is from a porcine source.

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. 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 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 System 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.

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.

EXPECTED CLINICAL BENEFITS

The iStent *inject* W provides a surgical option that has the ability to be performed at the same time as cataract surgery or as a standalone procedure (i.e., without cataract) for assisting in the delay of open-angle glaucoma disease progression and thereby preserving visual function and preventing future visual field loss.

EXPECTED LIFETIME

The iStent *inject* W is designed to last throughout the patient's lifetime.

PERFORMANCE CHARACTERISTICS

The iStent *inject* W is designed to provide clinical performance of IOP lowering for at least 12 months.

The Summary of Safety and Clinical Performance of the iS2 with UDI-DI 00853704002326 can be found at:
https://ec.europa.eu/tools/eudamed/#/screen/search-device.

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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. Recommended incision location is the temporal peripheral cornea for either eye. Ophthalmic 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 insertion steps are as follows: With the gonioprism 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 auto-retracts exposing the Insertion Tube and Trocar tip. Advance the Insertion Tube to the pupillary margin toward the targeted trabecular meshwork tissue (i.e., the *ab interno* approach). Take care to avoid contact with the IOL, iris, or cornea.

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4) Place a commercially available gonioprism on the cornea and position the patient and surgical microscope as needed to visualize the trabecular meshwork through the gonioprism 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 traverses over the trocar through to Schlemm's canal.
6) Gently hold the Insertion Tube against the TM and apply appropriate pressure to slightly indent or "dimple" the tissue (tissue should stretch just enough to form a "V" when pressing on the TM).
7) Slowly squeeze and hold down the Stent Delivery Button to automatically inject the stent head through the TM and into Schlemm's canal. Look through the window in the insertion tube to verify that the stent has been implanted properly.
8) Withdraw the injector straight back from the stent, and verify that the stent is well-positioned and secured in the TM.
9) Actuate the Singulator to prepare the next stent for implantation. Listen for two audible clicks, and verify that the next stent is visible in the window of the insertion tube.
10) Carefully relocate the tip of the injector approximately 2 clock hours away from the first stent for implantation of the second stent. Implant the next stent using the same procedure as the previous stent.
11) Remove the injector from the eye.
12) 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.
13) Inflate the anterior chamber with saline solution as needed to achieve normal physiologic pressure.
14) 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. Ideally, use a clear corneal incision measuring approximately 1.5mm in length is recommended.
3) Use viscoelastic to inflate the anterior chamber to create access to the stent's location, 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 form 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.
- Stent *inject* W stents are MR-Conditional; see MRI Information below.
- Physician training is required prior to use of the iStent *inject* W System. Training consists of:
  - Didactic session
  - Simulated implantation of iStent *inject* W System
  - Supervised iStent *inject* W System implantation of clinical cases until implantation proficiency is demonstrated.
- 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

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- 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 arising after the prescribed medication regimen is complete
- 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)

IMPLANT CARD

An implant identification card is supplied in the device packaging. This card should be given to the patient with instructions to keep as a permanent record of the implant and show to future health care providers. The implant card also identifies the stent as "MR Conditional" and should be shown to health care providers if the patient needs to undergo an MRI.

PRODUCT COMPLAINTS & SERIOUS INCIDENT REPORTING

Product complaints, incidents, and serious incidents should immediately be reported to Glaukos Medical Safety at MedicalSafety@glaukos.com. Serious incidents should also be reported to the National Competent Authority of the Member State where the user/patient resides.

MRI SAFETY INFORMATION

Static magnetic field of 3-Tesla or less:

Non-clinical testing has demonstrated that the iStent *inject* W System stents, Model iS2 is MR-Conditional.

A patient with this device can be scanned safely in an MR system meeting the following conditions:
- Static magnetic field: 3-Tesla or less
- Maximum spatial 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* W System stents, Model iS2 are 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 using a gradient echo pulse sequence and a 3.0 T MRI system.

Static magnetic field of 7-Tesla, ONLY:

Non-clinical testing demonstrated that the iStent *inject* W System stents, Model iS2are 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 7-Tesla, 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 7-Tesla MR system.

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LABELING

The following symbols are used on the device packaging.

Symbol	*Definition*
REF	Catalogue/Model Number
SN	Serial Number (for the stent)
LOT	Batch code
	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
QTY	Quantity
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
	Single *sterile* barrier system with protective Packaging outside
	Date of manufacture

EC REP

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