The iStent inject® System contains two pieces that are manufactured from titanium (Ti6Al4V ELI) and are coated with stearamine heparin (Stearalkonium heparin (note: the heparin is from a porcine source)). The stent has a single piece design, is approximately 360 microns in height and 230 microns in diameter. The injector has been designed by Glaukos Corporation to hold two iStent® Micro Bypass 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® System is provided in a blister tray (only the inner contents of the blister tray is sterile). Two stents are already assembled onto the single-use injector. The blister tray contains a product identification information. Each stent within the injector system is serialized and a lot number for the injector is clearly indicated on the outside of the unit carton. iStent inject® System is sterilized by gamma irradiation.

The expiration date on the device package (tray id) is the expiration date on the assembly. In addition, there is a sterilization expiration date that is clearly indicated on the outside of the unit carton. Sterility is guaranteed if the tray seal is not broken before the sterilization date until the expiration date. This device is intended for single-use and the expiration date indicated sterilization expiration date.

INDICATIONS FOR USE
The iStent inject® Trabecular Micro-Bypass System is intended to reduce intraocular pressure in adult patients diagnosed with mild to moderate primary open-angle glaucoma or ocular hypertension treated with ocular hypotensive medication. The device can be implanted with or without cataract surgery.

CONTRAINDICATIONS
The iStent inject® System is contraindicated under the following circumstances or conditions:

- In eyes with primary angle closure glaucoma, or secondary angle-closure glaucoma, iridocorneal angle occlusion, because the device would not be expected to work in such situations.
- In patients with retrolubular tumor, thyroid eye disease, Sturge-Weber Syndrome or any of the following conditions that may cause elevated episcleral venous pressure

INSTRUCTIONS FOR USE
1) Make a corneal incision. Trabecular micro-bypass device that will ensure it remains inflated.
2) Place a gonioscope on the corneal wound to visualize the trabecular meshwork, through the gonioscope, on the nasal side of the eye.
3) Enter the eye with the iStent inject.
4) Press the retraction (back) button to draw back the insert sleeve and expose the trabecular meshwork and trocar.
5) Advance the trocar tip to the center of the trabecular meshwork.
6) Press the trigger (front) button to inject the device into the trabecular meshwork and into Schlemm's Canal.
7) Look through the slot in the insertion tube and verify the device 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 anterior chamber to remove all viscoelastic, and then open the post-ocular edge of the incision as needed to facilitate complete removal of viscoelastic.
11) Infuse 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. Ideally, use a clear corneal incision measuring approximately 1.5mm in length.
3) Use viscoelastic to visualize the location of the stent in the anterior chamber.
4) Insert a micro forceps device through the corneal incision.
5) Open the jaws by pressing the trigger of the micro forceps device until the stent can be grasped in any convenient and secure location.
6) Remove the stent in the jaws of the micro forceps device from the eye taking care not to contact the iris, cornea, or lens, if possible.
7) Irrigate the anterior chamber with balanced salt solution (BSS) through the anterior chamber to remove all viscoelastic. Press down on the posterior edge of the incision as needed to facilitate complete removal of viscoelastic.
8) Infuse the anterior chamber with saline solution as needed to achieve normal physiologic pressure.
9) Seal the corneal incision is sealed.

WARNINGS/PRECAUTIONS
• For prescription use only.
• This device has been studied in patients with uveitic glaucoma.
• Patients should be informed that placement of the stents, without modification or change in phakic patients, can enhance the formation or progression of cataract.
• Do not use the devices if the blister tray has been exposed to light.
• Do not use the devices if the blister tray has been opened or the packaging appeared damaged. In such cases, the sterility of the device may be compromised.
• Due to the sharpness of certain injector components (i.e. the insertion tube) care should be exercised to grasp the injector body. Dispose of device sharp parts.
• iStent inject® is MR-Conditional; see MRI Information below.
• Each iStent inject® Bypass System is sterilized to achieve normal physiologic pressure.
• Do not reuse the stent(s) or injector, as this may result in infection and/or intraocular infection.

The iStent inject® System is designed by Glaukos Corporation and is MR-Conditional; see MRI Information below.

TABLE 1

<table>
<thead>
<tr>
<th>Device</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G2-M-IS-AS</td>
<td>Glaukos iStent inject System; all with 2 (2) Reparative Micro Bypass Stents (Model: GTS400) preloaded in single-use injector</td>
</tr>
</tbody>
</table>
postoperative adverse events as having been under “Potential Complications.”

There are no known compatibility issues with the iStent inject 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 components of these 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 inadequately maintained after surgery, the surgeon should consider an appropriate treatment regimen to reduce intraocular pressure.

POTENTIAL COMPLICATIONS

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

Potential intraoperative events are as follows:

• Choroidal complication (hemorrhage or effusion)
• Crystalline lens touched by injector
• Posterior capsular bag rupture, in case of combined cataract surgery

Potential postoperative events are as follows:

• Cataract formation and/or cystoid macular edema
• IOL dislocation (in pseudophakic eyes)
• Stent obstruction or malposition
• Stent repositioning or removal
• IOL repositioning or removal
• Trabeculectomy

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 spatial magnetic field of 50-gauss/cm (extrapolated)
• Maximum spatial RF magnetic field of 10-gauss/cm (extrapolated)
• Maximum temporal magnetic field of 10-gauss/cm/sec (extrapolated)
• Maximum spatial magnetic field of 10-gauss/cm (extrapolated)
• Maximum spatial gradient magnetic field of 10,000-gauss/cm (extrapolated) or less
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• Maximum spatial RF magnetic field of 10-gauss/cm (extrapolated)
• Maximum temporal magnetic field of 10-gauss/cm/sec (extrapolated)

• Static magnetic field of 3-Tesla or less
• Maximum spatial magnetic field of 4,000-gauss/cm (extrapolated)
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg for the 15 minutes of scanning of continuous imaging (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.

LABELING

The following symbols are used on the device packaging.