**DEVICE DESCRIPTION**

**CONTRAINDICATIONS**

- Surgery.
- Implanted with or without cataract medication. The device can be treated with ocular hypotensive medication.
- Mild to moderate primary open-angle glaucoma in adult patients diagnosed with pressure.
- The Bypass System is intended to inject Trabecular 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 injector contains a sterile stent provided in a blister tray (only the inner contents of the blister are sterile). Two stents are already assembled onto the single-use injector. The blister tray lid is labeled with the required product identification information. Each stent within the injector system is serialized and a lot number for the stent is clearly indicated on the labeling. The iStent inject System is sterilized by gamma irradiation.

The expiration date on the device pack dates to the expiration date of the outer packaging. The expiration date is clearly indicated on the labeling. The expiration date on the device pack dates to the expiration date of the outer packaging. The expiration date is clearly indicated on the labeling.

**INDICATIONS FOR USE**

The iStent inject Trabecular Micro-Bypass System is intended to reduce intraocular pressure in patients with mild to moderate primary open-angle glaucoma.

**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, including neovascular glaucoma, 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 other type of condition that may cause elevated episcleral venous pressure.

**INSTRUCTIONS FOR USE**

1. Make a corneal incision.
2. Prep the patient as one would for implantation surgery.
3. Use viscoelastic to inflate the corneal wound as needed to ensure it remains inflated.
4. Slit lamp and gonioscope, on the nasal side of the limbus, to visualize the trabecular meshwork.
5. Use viscoelastic.
6. Press the trigger (front) button to inject the stent into the anterior chamber to create a patent opening in the trabecular meshwork.
7. Look through the slot in the inserter body to confirm the stent is securely in place.
8. While remaining in the eye, irrigate the anterior chamber with balanced salt solution (BSS) through the corneal incision to remove viscoelastic. Press down on the posterior edge of the iris, cornea, or lens, if possible.
9. Irrigate the anterior chamber with balanced salt solution (BSS) through the corneal wound to achieve normal physiologic pressure.
10. Ensure that the corneal incision is sealed.

**WARNING/PRECAUTIONS**

- Observation of surgical cases
- Webinar
- The iStent inject System, and consists of three main parts:
  - Webinar
  - Didactic session with Glaukos surgical representative
  - Observation of surgical cases by Glaukos representative until implantation technique and efficacy of the device is demonstrated
- Do not remove the stent(s) from the inserter, as this may result in infection and/or intraocular inflammation, as well as occurrence of postoperative adverse events.

**CATALOGUE# Description**

<table>
<thead>
<tr>
<th>Catalogue #</th>
<th>Description</th>
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<tbody>
<tr>
<td>G2 H1-MvAS</td>
<td>Glaukos (IStent inject System, 1 AS, with 2 [2] heparin coated Bypass Stents (Model GTS400) already assembled onto single-use injector)</td>
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**STORAGE**

The iStent Injectable Trabecular Micro-Bypass System, and consists of three main parts:

1. Prep the patient as one would for implantation surgery.
2. Re-open the stent(s) in the preferred location in order to reach the stent. Ideally, use a clear view of the desired position deviating approximately 1.5mm in length.
3. Use viscoelastic to confirm the anterior chamber to create access to the stent’s location, move the stent away from a delicate structure if loose, and/or protect the cornea.
4. Use a gonioscope if needed to visualize the location of the stent in the anterior chamber.
5. Insert a GTS100i inserter through the corneal incision.
6. Open the jaws by pressing the trigger (front) button to access the stent. The stent can be grasped in a convenient and secure location.
7. Remove the stent from the GTS100i inserter by eye taking care not to contact the iris, cornea, or lens, if possible.
8. Irrigate the anterior chamber with balanced salt solution (BSS) through the corneal wound to remove all viscoelastic.
9. Due to the sharpness of certain inserter, as this may result in infection and/or intraocular inflammation, as well as occurrence of postoperative adverse events.
STORAGE REQUIREMENTS

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

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the 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 3-Tesla or less
- Maximum spatial magnetic field of 4,000-gauss/cm (40 T/m) (extrapolated)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scans (i.e., per pulse sequence)
- Use of a transmit/receive RF head coil, only

MRI-Related Testing

In non-clinical testing, the device produced a temperature rise of less than 1°C during MRI performed for 15 minutes of scans (i.e., per pulse sequence) in a 7-Tesla/298 MHz MRI system (Philips Achieva, Philips Healthcare, Cleveland, OH) at transmit/receive RF head coil.

LABELING

The following symbols are used on the device packaging.