

IStent infinite® Trabecular Micro-Bypass System
INSTRUCTIONS FOR USEP-000588
Rev 3/07/24**DEVICE DESCRIPTION**

Catalogue #	Description
iS3	Glaikos® IStent infinite® System Model iS3 with three (3) G2-W stent/scleralonium heparin coated Trabecular Micro-Bypass Stents preloaded in one injector.

The IStent infinite® System contains three individual stents that are manufactured from implantable poly-L-lactide and are coated with scleralonium (heparin) (not a prescription source). The stent has a single piece design, is approximately 360 micrometers in height and 360 micrometers in diameter. The injector has been designed by Glaikos Corporation to implant three 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. This device should not be used to stent a passage through the trabecular meshwork to allow for an increase in the facility of outflow and a subsequent reduction in intraocular pressure.

HOW SUPPLIED

Each IStent infinite System is provided sterile in a blister tray (only the inner contents of the blister tray are sterile). Three 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 infinite System is supplied by Glaikos Corporation.

The expiration date on the device packaging (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.

POTENTIAL COMPLICATIONS

The IStent infinite System is contraindicated under the following circumstances or conditions that may cause elevated intraocular pressure:

- o The IStent infinite System is contraindicated under the following circumstances or conditions that may cause elevated intraocular pressure and/or would benefit from glaucoma medication reduction:

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

CONTRAINDICATIONS

The IStent infinite System is contraindicated under the following circumstances or conditions that may cause elevated intraocular pressure:

- o The 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:

INSTRUCTIONS FOR USE

1) Remove the Steril 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 the 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 infinite injector insertion steps are as follows: With the gonioscope 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 anterior approach). Take care to avoid contact with the IOI, iris, or cornea.

4) Place the gonioscope on the cornea and position the patient and surgical microscope as needed to visualize the trabecular meshwork through the gonioscope 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 penetrate the TM, but will remain in the tissue to act as an axial guide for the stent as the stent travels through the trocar toward Schlemm's canal.

6) Gently hold the injector tube above the eye and apply appropriate pressure to slightly flatten or "dimple" the tube (the tube should stretch just enough to form a "V" when pressing on the TM).

7) Slowly squeeze and hold down the Steril 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 Singularator to prepare the next stent for implantation. Listen for two audible clicks to verify that the next stent is visible in the insertion tube.

10) Carefully re-latch the tip of the injector approximately 2 clock positions away from the first stent for implantation of the second stent. Implant the next stent using the same procedure as the previous stent.

11) Repeat the previous step for the third stent, placing the third stent approximately 2 clock hours away from either of the first two stents.

12) Remove the injector from the eye.

13) 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.

14) Inflate the anterior chamber with saline solution as needed to achieve normal physiologic pressure.

15) 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, move the stent away from a delicate structure and/or protect intracular tissues.

4) Use a gonioscope 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 been developed in patients with uveitic glaucoma; the packaging appears damaged; in such cases, the sterility of the device may be compromised.
- Due to the shape 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 trash can.
- IStent infinite is MTR-Conditional; see MRI Information below.
- Physician training is required prior to use of the IStent infinite System.
- Do not re-use the stents 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 infinite 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 patient postoperatively for proper maintenance of intraocular pressure. If intraocular pressure is not adequately maintained after surgery, the surgeon should consider an appropriate treatment 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.

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POTENTIAL COMPLICATIONS

The IStent infinite System is contraindicated under the following circumstances or conditions that may cause elevated 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 treatment with glaucoma medications and/or conventional glaucoma surgery.

CONTRAINDICATIONS

The IStent infinite System is contraindicated under the following circumstances or conditions that may cause elevated intraocular pressure:

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3) The IStent infinite injector insertion steps are as follows: With the gonioscope 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 anterior approach). Take care to avoid contact with the IOI, iris, or cornea.

4) Place the gonioscope on the cornea and position the patient and surgical microscope as needed to visualize the trabecular meshwork through the gonioscope 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 penetrate the TM, but will remain in the tissue to act as an axial guide for the stent as the stent travels through the trocar toward Schlemm's canal.

6) Gently hold the injector tube above the eye and apply appropriate pressure to slightly flatten or "dimple" the tube (the tube should stretch just enough to form a "V" when pressing on the TM).

7) Slowly squeeze and hold down the Steril 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 Singularator to prepare the next stent for implantation. Listen for two audible clicks to verify that the next stent is visible in the insertion tube.

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