ISTENT® TRABECULAR MICRO-BYPASS STENT SYSTEM INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The iStent® Trabecular Micro-Bypass Stent Model GTS100R/L is an intraocular stent that is manufactured from titanium (Ti6Al4V ELI) and is coated with stearalkonium heparin (note: the heparin is from a porcine source). The stent has a single piece design, is 1.0 mm in length, 0.33 mm in height, with a snorkel length of 0.25 mm, and a nominal snorkel bore diameter of 120µm. The implant is intended for placement into Schlemm's canal, which creates a patent opening in the trabecular meshwork and re-establishes normal physiological outflow. The inserter has been designed by Glaukos Corporation to hold the implant and to release the implant once it has been inserted within Schlemm's canal. Two model numbers (GTS100L and GTS100R) are available. The last digit of these model numbers (L and R) correlates to a left-flow stent and a right-flow stent. The stents are identical except the "foot" faces opposite directions in order to facilitate nasal stent placement and to optimize distal flow through collector channels. Model GTS100L is designed for the left eye, and Model GTS100R is designed for the right eye.

Glaukos® Trabecular Micro-Bypass Stent System

Catalogue #	Description
GTS100L	Left-flow iStent attached to disposable inserter
GTS100R	Right-flow iStent attached to disposable inserter

HOW SUPPLIED

Each iStent Trabecular Micro-Bypass Stent System is provided sterile in a blister tray (only the inner contents of the blister tray are sterile). The stent is already assembled onto a single-use inserter (Model GTS100i). The blister tray lid is labeled with the required product identification information. The stent is individually serialized and the serial number is provided on the labeling. The iStent Trabecular Micro-Bypass Stent 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.

INDICATIONS FOR USE

The iStent Trabecular Micro-Bypass Stent System is intended to reduce intraocular pressure in adult patients diagnosed with mild to moderate primary open-angle glaucoma (POAG) currently treated with ocular hypotensive medication. The device can be implanted with or without cataract surgery.

CONTRAINDICATIONS

The iStent Trabecular Micro-Bypass Stent 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

INSTRUCTIONS FOR USE

1. A corneal incision is made and the anterior chamber stabilized to ensure it remains inflated.
2. Place a 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. The inserter, with the stent attached, is placed through the corneal incision. The inserter is then guided across the anterior chamber and the leading edge (tip) of the stent is inserted into the trabecular meshwork. The tip of the stent will make a "self-trephining" incision.
4. Continuing insertion, the remainder of the stent is slid into the Schlemm's Canal. Once the stent is securely in place, the release button on the inserter handle should be pushed to disengage the stent. Then, the inserter is removed from the eye.
5. Before concluding the procedure, visual confirmation of stent placement by gonioscopy must be performed.
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.
7. Inflate the anterior chamber with saline solution as needed to achieve normal physiologic pressure.
8. Ensure that the corneal incision is sealed.

Retrieval of an Implanted Stent

If the surgeon determines that another GTS100i inserter is required to grasp a stent (i.e., the original inserter from the stent system is no longer available or not used), the Model GTS100i inserter may be used by the surgeon as follows:

1. Similar to the initial implant procedure, visualize the location of the iStent using a goniolens.
2. Enter the eye through a clear corneal incision.
3. Advance to the location of the iStent, and depress the inserter button to open the inserter jaws.
4. While holding down the release button, position the snorkel of the stent in the inserter, and then release the release button to grasp the snorkel of the stent. Once the stent is in the inserter, it can then be implanted as described in Step 4 above, or removed from the eye. Care should be exercised when exiting the wound.

WARNINGS/PRECAUTIONS

- For prescription use only.
- This device has not been studied in patients with uveitic glaucoma.
- Patients should be informed that placement of the stents, without concomitant cataract surgery in phakic patients, can enhance the formation or progression of cataract.
- Do not use the devices if the Tyvek® lid has been opened or the packaging appears damaged. In such cases, the sterility of the device may be compromised.
- iStent is MR-Conditional; see MRI Information below.
- Physician training by Glaukos personnel is required prior to use of this device. Training consists of:
  - Didactic session
  - Simulated implantation of iStent
  - Supervised iStent implantation of clinical cases until implantation proficiency is demonstrated
- Do not re-use the stent(s) or inserter, 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 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.

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 inserter
- 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-pre-existing)
- 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
- Significant loss of best corrected visual acuity (BCVA)
- Stent dislocation or malposition
- Stent obstruction

STORAGE REQUIREMENTS

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

MRI SAFETY INFORMATION

MR

Static magnetic field of 3-Tesla or less:

Non-clinical testing has demonstrated that the iStent Trabecular Micro-Bypass Stent (Models GTS100R and GTS100L) is MR-Conditional.

A patient with this device can be safely scanned 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 Trabecular Micro-Bypass Stent (Models GTS100R and GTS100L) is not expected to produce a clinically significant temperature rise after 15 minutes of continuous scanning (i.e., per pulse sequence).

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 using a gradient echo pulse sequence and a 3-Tesla MRI system.

Static magnetic field of 7-Tesla, ONLY:

Non-clinical testing demonstrated that the iStent Trabecular Micro-Bypass Stent (Models GTS100R and GTS100L) 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 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 Acheiva, 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.

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
2	Do not re-use
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
MR	MR Conditional
Rx Only	For prescription use only
	Consult Instructions For Use
	Manufacturer's Company Address

Manufacturer
Glaukos Corporation
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