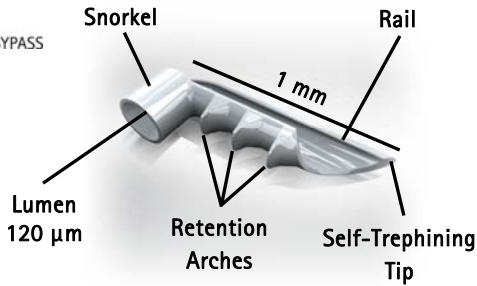
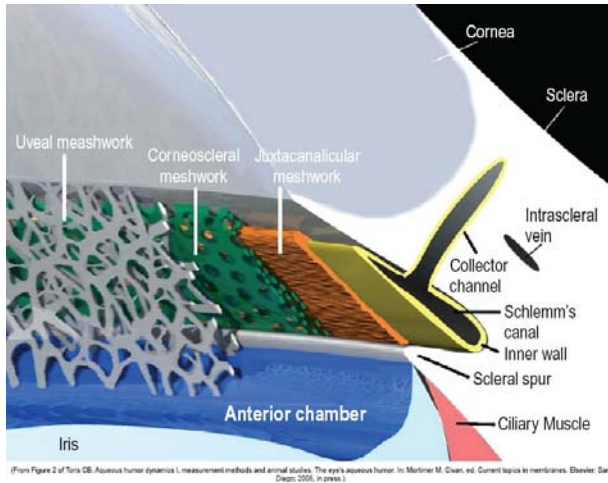


iStent[®] Implantation Procedure

iStent[®]
TRABECULAR MICRO-BYPASS
Design



Anatomy



iStent Indications for Use

The iStent Trabecular Micro-Bypass Stent Model GTS100R/L is indicated for use in conjunction with cataract surgery for the reduction of IOP in subjects with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

iStent Contraindications (Unsuitable Patients)

The iStent Trabecular Micro-Bypass Stent is contraindicated under the following circumstances or conditions:

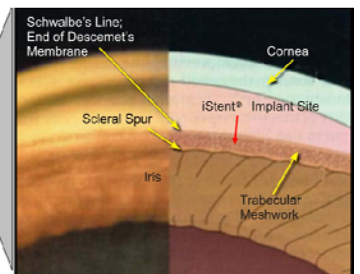
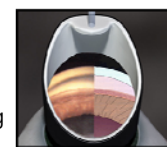
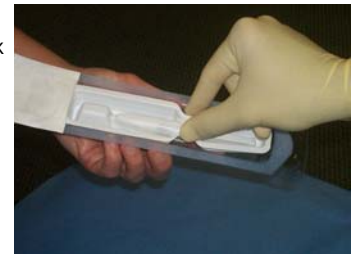
- In patients with angle closure glaucoma and other secondary glaucomas such as neovascular glaucoma and uveitic glaucoma.
- In patients with retrobulbar tumor, chronic inflammatory disease, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition where the trabecular meshwork, Schlemm's Canal or collector channels at the implant site are compromised.

Cataract Surgery

- Follow your standard practice or hospital cataract surgery protocol.
- Anesthetize the eye using standard operating procedures.
- Remove the cataract using standard phacoemulsification techniques and insert a commercially available IOL.
- Do not implant the iStent if there are any significant complications, including but not limited to severe corneal burn, vitreous removal/vitreotomy required, corneal injuries, or complications requiring the placement of an anterior chamber lens.

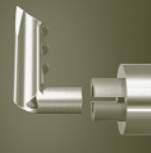
iStent Surgery

- To increase visualization after cataract surgery deepen the angle by instilling an intracameral miotic.
- The iStent is designed for nasal placement; perform the implantation from the temporal side of the head.
- Reposition the surgical microscope to visualize the trabecular meshwork by tilting the microscope 30° to 35° towards the surgeon. If possible, tilt the patients head 30° to 35° away from the surgeon.
- Check the iStent package to ensure you have the proper stent for the patient.
- Do not use the device if the Tyvek lid has been opened or the packaging appears damaged; the sterility of the device may be compromised. Look through the clear peel pouch package to ensure that the iStent is on the inserter and is correctly oriented (Left or Right) before pulling back the Tyvek lid.
- Place the iStent inserter on the sterile field (DO NOT DROP). Rinse the stent and the inserter tip with sterile Balanced Salt Solution (BSS).
- Increase the microscope magnification to 10-12x. Apply viscoelastic to the cornea and place the gonioprism on the eye. Be careful not to push on the cornea as it may cause folds that distort your vision. Inspect the angle with the gonioprism, focusing on the landmarks in the angle of the eye (pictured below). Look up from the iris root to find the scleral spur (white line); then look for Schwalbe's line (white line) down from the cornea. The trabecular meshwork (red/brown line) is between the scleral spur and Schwalbe's line. Schlemm's canal is located behind the trabecular meshwork.
- Be sure to visualize the target implant site before placing the inserter in the eye for implantation.



iStent is a registered trademark of Glaukos[®] Corporation, Laguna Hills, CA USA

iStent[®] Implantation Procedure

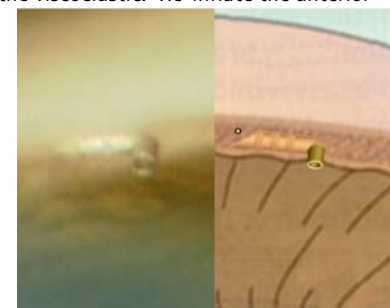
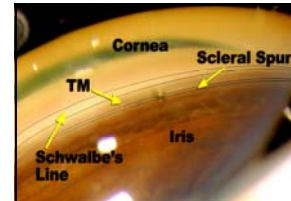
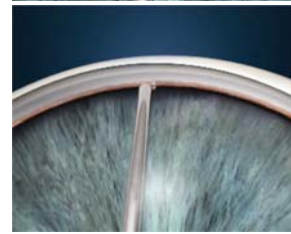
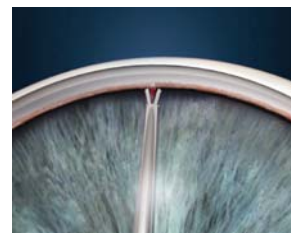


Insertion of the iStent

- Inject viscoelastic to assist with chamber maintenance.
- Prior to entering the eye hold the inserter like a pencil, placing your index finger on the release trigger (taking your eyes off of the anatomy to find the release button while in the eye can cause challenges with stent placement).
- Insert the iStent inserter through the cataract surgery incision and move the inserter across the pupillary margin towards the nasal position (3 - 4 o'clock for the right eye; 8 - 9 o'clock for the left eye).
- Place the gonioscope on the cornea.
- Locate the trabecular meshwork and look for hyper-pigmented areas (likely associated with collector channels).
- Advance the stent and position the tip over the top third of the trabecular meshwork, just above the scleral spur.
- Approach at a 15° angle.
- Lightly touch the trabecular meshwork with the iStent as this allows one to gauge the depth perception of the inserter in reference to the targeted implantation site.
- Be careful and decisive during implantation of the stent. Hesitation marks may release blood and obscure the view, damage the trabecular meshwork and/or impair the surgical procedure.
- Using the incision as a fulcrum, rotate the inserter to engage the trabecular meshwork with the self-trephining tip of the stent.
- Once the tissue is engaged, pause (to let Schlemm's canal reform) and penetrate the trabecular meshwork with the tip. Do not force entry.
- Gently slide the leading edge of the stent through the trabecular meshwork and into Schlemm's canal. During surgery, the iStent should slide into Schlemm's canal with minimal resistance. Resistance increases as the stent encounters the scleral wall. If resistance increases, then stop, backup slightly and gently slide into Schlemm's canal. Use a slight lifting motion similar to placing an intravenous line to insert the stent.
- Significant resistance indicates that a false passage has been created and the surgeon should stop. Move one half hour inferior along the trabecular meshwork and try again (collector channels are concentrated in the inferior half of the eye).
- Pushing posteriorly during implantation may malposition the stent into the scleral spur.



- If your first attempt is unsuccessful, reacquire the stent with the inserter and re-implant one half hour inferiorly and the result will be about one hour below horizontal. Aiming superiorly on the second try can cause the stent to direct fluid to the damaged meshwork which may scar.
- Once the trabecular meshwork touches the snorkel, carefully release the stent by pushing the release button on the inserter, making sure to avoid any lateral forces during the release of the stent.
- Blood may reflux after stent placement, indicating that the stent has been properly placed.
- Once the iStent is in Schlemm's canal gently tap the back of it with the inserter or the viscoelastic cannula as this drops the heel of the snorkel completely into the canal. The heel of the snorkel will not drop into the canal without a gentle push. To see the iStent more clearly prior to tapping it into the canal use viscoelastic to clear any blood reflux obstructing the view.
- Before withdrawing the inserter, increase magnification and view the stent to verify correct positioning.
- The implanted stent should be parallel to the trabecular meshwork. Gently nudge the snorkel of the stent and make sure that it returns to its original position; the body of the stent will move horizontally along its axis, sliding inside the canal. This verifies that the rails on the base of the stent are located on the back wall of Schlemm's canal; thereby confirming the snorkel axis is parallel with the iris plane. If it is not correctly seated, the body of the stent will move sideways. The stent snorkel should extend out of Schlemm's canal and the retention arches should appear cloudy. The snorkel opening should be clear and the snorkel shaft must be completely surrounded by meshwork.
- Remove the inserter carefully and then irrigate and aspirate the anterior chamber to remove the viscoelastic. Re-inflate the anterior chamber to achieve physiologic pressure and to ensure that the corneal incision is watertight. Press down on the posterior edge of the corneal incision (as needed) to ensure all the viscoelastic is completely removed.



Note: Refer to the product IFU for complete prescribing information.

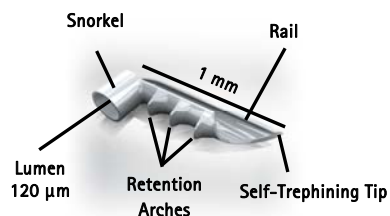


I. Product Description



The iStent Trabecular Micro-Bypass is designed to be inserted *ab interno* through a small temporal clear corneal incision and to fit the anatomy of the eye's outflow system. Its purpose is to stent open the trabecular meshwork, thereby increasing the outflow facility of the aqueous humor and reducing intraocular pressure (IOP).

The cylindrical part of the device (the snorkel) is designed to extend slightly into the anterior chamber. The inner bore diameter of the snorkel is 120 µm. Aqueous humor flows through the snorkel and into the device lumen, which is seated in Schlemm's canal; thereby accessing the natural physiological outflow pathways.



The iStent device is made of titanium and is heparin coated. The device is approximately 1 mm in length and 0.3 mm in height. Two iStent orientations are available - one for the right eye (OD) and one for the

left eye (OS). The iStent device is designed for nasal placement, with the portion of the iStent located inside Schlemm's canal pointing toward the feet of the patient. The iStent dimensions are customized for a natural fit within the canal. Three retention arches ensure secure placement, and the rail design protects and accesses the underlying collector channels.



The iStent comes preloaded in the single-use (disposable) sterile inserter in order to allow for easy *ab interno* insertion into Schlemm's canal. The inserter is designed to hold the iStent and then release it once the iStent is inserted into the canal. Releasing the iStent is accomplished by pushing the button on the body of the inserter instrument. In the event of a premature release or improper iStent placement, the inserter may be used to retrieve the iStent.

iStent has a Canadian medical device license and is indicated for use in conjunction with cataract surgery for the reduction of IOP in subjects with mild to moderate open-angle glaucoma being treated with ocular hypotensive medication. The iStent is inserted *ab interno* through the clear corneal phaco incision and can be

performed under topical anesthesia. The procedure spares the conjunctiva and scleral tissue; therefore preserving the potential for future glaucoma treatment options. The iStent is non-ferromagnetic, therefore there are no known risks for MRI procedures. The one-step, self-trephining tip eliminates the need for a separate trabecular meshwork incision step.

II. Material

iStent



The iStent is made from highly inert, implant-grade titanium. It is supplied sterile and pyrogen-free. It has a thin coating of heparin on both the external surfaces as well as the internal lumen. The heparin coating is used to improve the wetting of the implant surface, particularly the lumen. It is intended to promote self-priming and to facilitate outflow for the aqueous humor from the anterior chamber through the iStent into Schlemm's canal. The one-time application of heparin onto the titanium iStent is at a level that even with full theoretical absorption is unlikely to reach meaningful systemic therapeutic concentrations. The iStent has been thoroughly tested for biocompatibility in accordance with the requirements of ISO 10993.

Product Information Sheet

Inserter



The inserter is a precision surgical instrument designed specifically to hold, implant, position, retrieve, or adjust the iStent. It is manufactured from a combination of precision-machined surgical stainless steels and injection molded plastics to the highest quality standards. The iStent® system is supplied sterile and pyrogen free and has been thoroughly tested for biocompatibility in accordance with the requirements of ISO 10993. The iStent system is assembled and packaged under strict ISO Class 7 cleanroom conditions.

III. Packaging



The Trabecular Micro-Bypass System, comprised of the pre-assembled iStent and the inserter instrument, is packaged in Glycol Modified Polyethylene Terephthalate (PETG) and High Density Polystyrene (HIPS) plastic trays with a Tyvek® lid. Tyvek®, PETG, HIPS, and the trays are compatible with the terminal sterilization process. The iStent is fitted to the finished inserters

holding mechanism and the system is then sterilized by gamma irradiation at a certified contract sterilization facility. Glaukos® requires proof of sterilization and dosage for each shipment. Both the iStent and the tip of the inserter are sampled on every batch to ensure they are non-pyrogenic.

IV. Quality System

Glaukos obtained ISO certification to 13485:1996 in November of 2002, by Det Norske Veritas (DNV) Certification Services and has recently upgraded their certification to 13485:2003 with BSI Management Systems. Among others, Glaukos complies with the following standards/guidance documents:

- GCP/ISO 14155 Clinical investigation of medical devices for human subjects.
- ISO 11137-1 Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- ISO 11137-2 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.
- ISO 11137-3 Sterilization of health care products -- Radiation -- Part 3: Guidance on dosimetric aspects.
- ISO 14971 Medical devices -- Application of risk management to medical devices.

- EN980/EN1041/ISO 15223 Medical devices -- Symbols to be used with medical device labels, labeling, and information to be supplied.

V. Approvals

Medical device licenses for the iStent (GTS100R/L) and stand-alone inserter (GTS100i) were issued by Health Canada in 2009.

Glaukos was granted CE Mark 0434 on August 19, 2004, and this certification is valid until August 19, 2014. Yearly audits are held to verify the validity of this certification.

Not approved for sale in the US; currently in FDA clinical trials.

VI. Contact Information

Manufacturer

Glaukos Corporation
26051 Merit Circle, Suite 103
Laguna Hills, CA 92653 USA
Tel: 949.367.9600

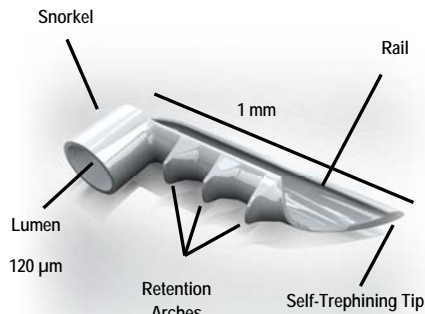
Authorized Canadian Representative

Labtician Ophthalmics
2140 Winston Park Drive
Unit #6
Oakville, Quebec L6H5V5
Canada
Tel: 905.829.0055

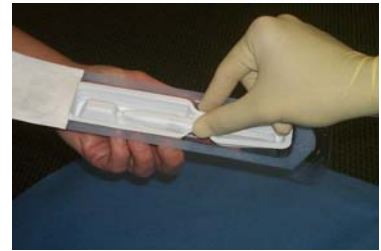
GLAUKOS®
Changing Perspectives

iStent® Surgical Card

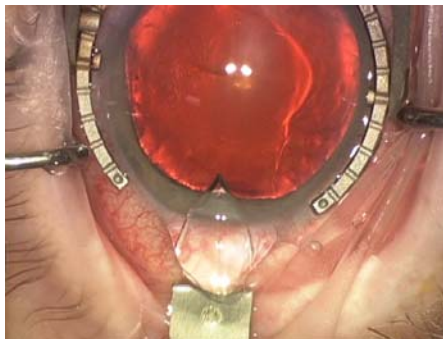
iStent®
TRABECULAR MICRO-BYPASS



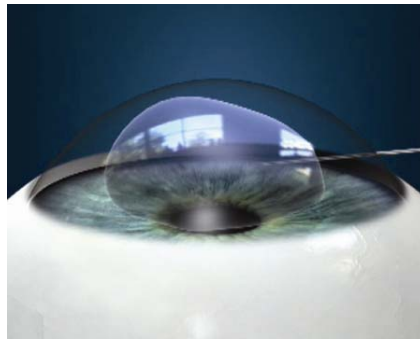
Step 1 - Patient Preparation: To increase visualization after cataract surgery deepen the angle with an intracameral miotic. Turn the patient's head away from the surgeon and tilt the microscope towards the surgeon.



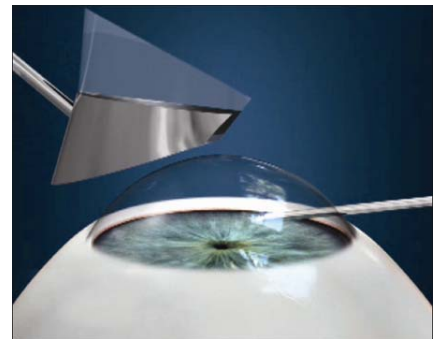
Step 2 - iStent Preparation: Check the iStent package to ensure you have the proper stent for the patient. Carefully open the iStent package. Rinse the stent and the inserter tip with sterile Balanced Salt Solution (BSS).



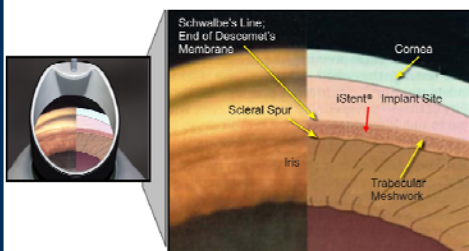
Step 3 - Clear Corneal Incision: Place a clear corneal incision temporally on the horizontal axis. Position the clear corneal incision as posterior as possible to ensure the inserter does not interfere with the gonioprism or the view of the anterior angle.



Step 4 - Viscoelastic: Inject viscoelastic into the anterior chamber to assist with chamber maintenance.



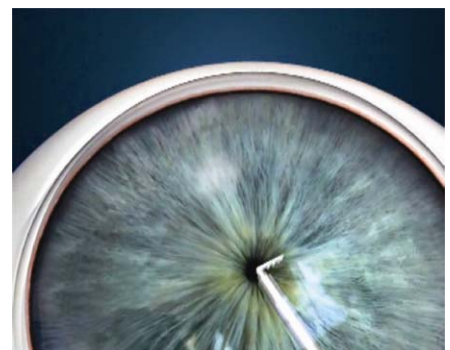
Step 5 - Visualization Preparation: Apply viscoelastic to the cornea and then place the gonioprism on the cornea. Zoom in (10-12x magnification) and inspect the angle and the target implantation site.



Step 6 - Target Implantation Site Visualization: Focus on the trabecular meshwork (red/brown line) located between the scleral spur and Schwalbe's line. Schlemm's canal is behind the trabecular meshwork. Aim to implant the stent in the top third of the trabecular meshwork and it will actually be implanted in the middle of the canal. The gonioprism creates an optical illusion and it causes the trabecular meshwork to appear flat although it is curved.

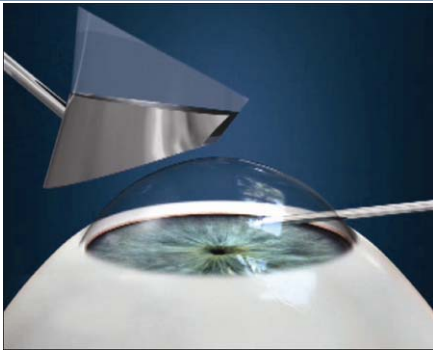


Step 7 - Holding the Inserter: Hold the inserter like a pencil before entering the eye. Keep your index finger on the release trigger; taking your eyes off of the anatomy to find the release button once in the eye can cause challenges with iStent placement.

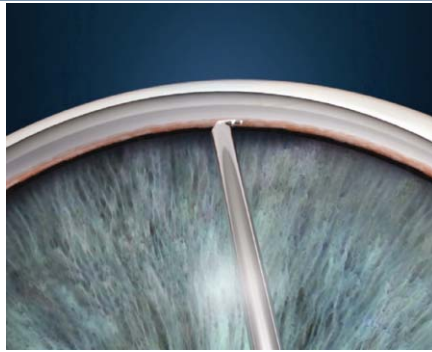


Step 8 - Inserting the iStent: Remove the gonioprism and then insert the iStent inserter through the incision and across the pupillary margin towards the nasal position (3 - 4 o'clock for the right eye; 8 - 9 o'clock for the left eye).

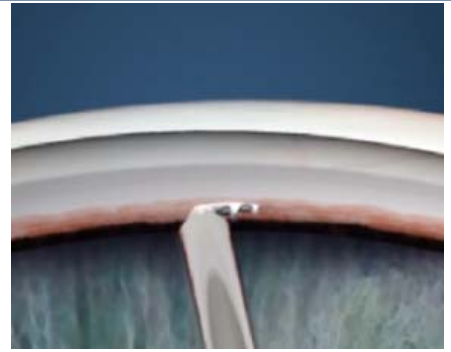
iStent® Surgical Card



Step 9 - Gonioprism: Place the gonioprism back on the eye and make sure the magnification is still at 10-12x. The trabecular meshwork should still be in focus as you begin implantation of the iStent device.



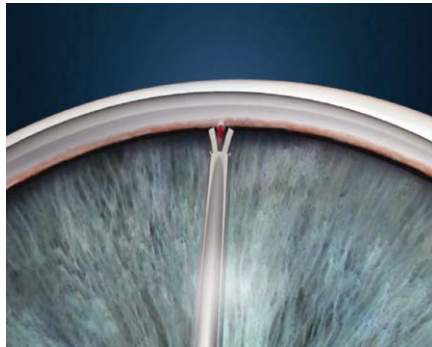
Step 10 - iStent Advancement: Advance the iStent and position the tip over the top third of the trabecular meshwork. iStent positioning is just above the scleral spur.



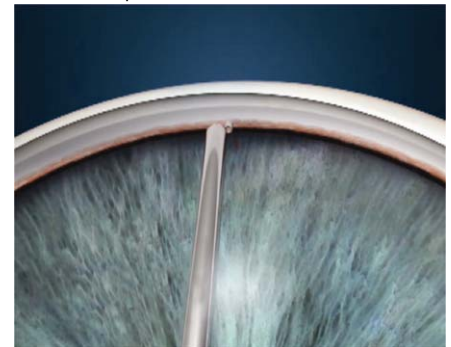
Step 11 - Implantation Approach: Approach at an angle of 15° and penetrate the trabecular meshwork. A pricking/lifting motion similar to placing an intravenous line is recommended to insert the stent. Using the incision as a fulcrum, rotate the inserter to engage the trabecular meshwork with the tip of the stent and place it into Schlemm's canal.



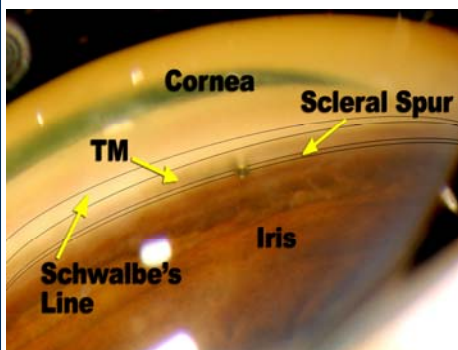
Step 12 - iStent Implantation: There is minimal resistance from the trabecular meshwork. Resistance increases as the stent encounters the scleral wall. When resistance increases, backup slightly and gently slide into Schlemm's canal. Significant resistance indicates creation of a false passageway.



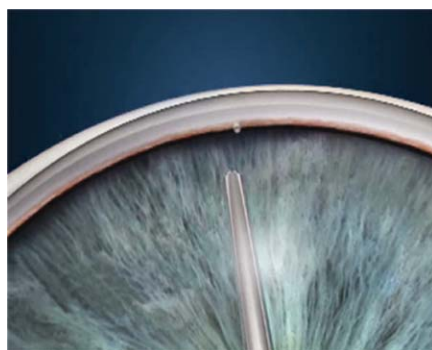
Step 13 - iStent Release: The stent should seat without significant resistance. Advance the device until the snorkel shaft meets the meshwork. Push the release button on the inserter to release the stent. Blood may reflux after stent placement.



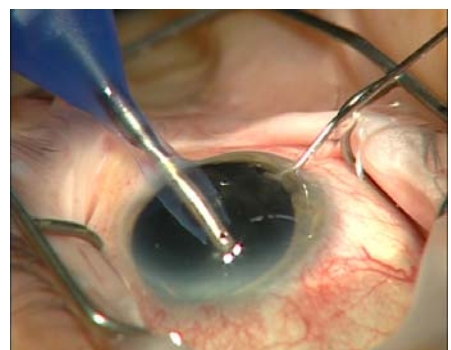
Step 14 - iStent Seating: The rails of the stent should seat against the scleral wall of Schlemm's canal. Tap the stent, using the iStent inserter or the cannula from the viscoelastic, to ensure the heel of the snorkel is well seated against the scleral wall and the snorkel is parallel to the iris plane.



Step 15 - iStent Position Verification: Increase magnification before withdrawing the inserter and view the stent to ensure correct positioning. The snorkel shaft must be completely surrounded by the trabecular meshwork and the tip of the snorkel must be unobstructed.



Step 16 - Inserter Removal: Carefully remove the iStent inserter from the eye.



Step 17 - Viscoelastic Removal: Remove all of the viscoelastic and make sure the corneal incision is watertight.