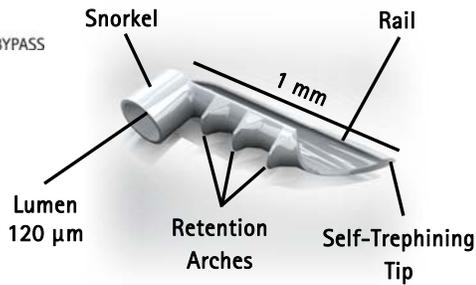


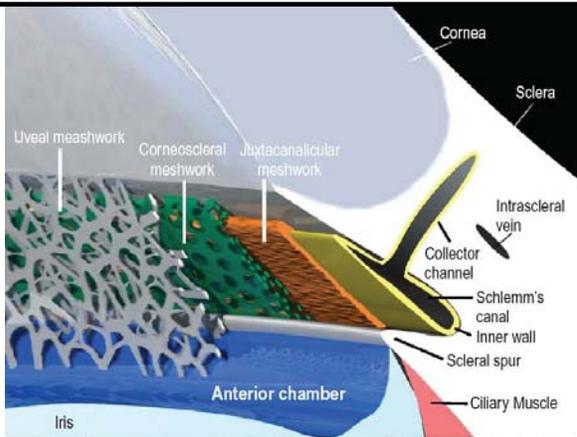
iStent[®] Implantation Procedure



Design



Anatomy



iStent Indications for Use

The iStent Trabecular Micro-Bypass Stent Model GTS100R/L is indicated for use alone or in conjunction with cataract surgery for the reduction of IOP and/or medication in subjects with primary open-angle glaucoma, pseudoexfoliative glaucoma or pigmentary glaucoma.

iStent Contraindications (Unsuitable Patients)

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

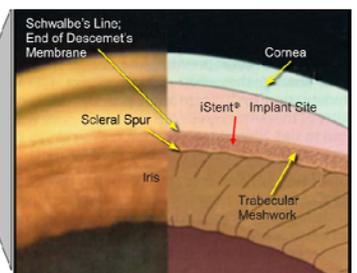
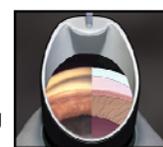
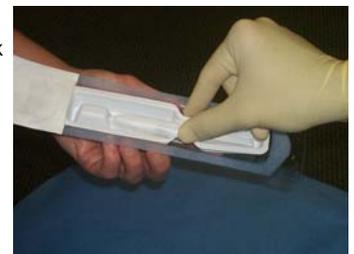
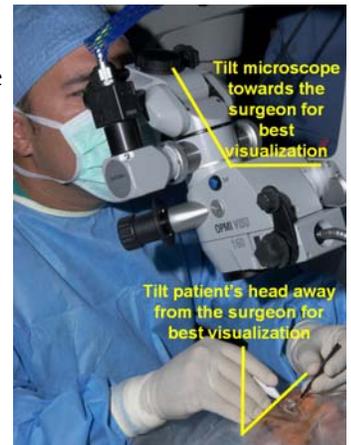
- In patients with angle closure glaucoma and other secondary glaucomas such as neovascular glaucoma and uveitic glaucoma.
- In patients with retrobulbar tumor, chronic inflammatory disease, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition where the trabecular meshwork, Schlemm's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

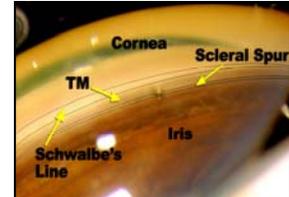
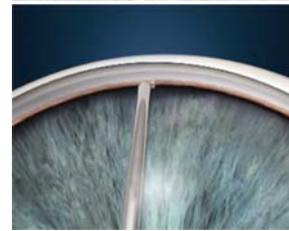
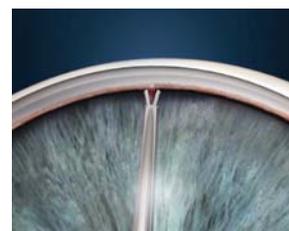


Insertion of the iStent

- 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.