DEVICE DESCRIPTION

The iStent Trabecular Micro-Bypass Stent (Model GTS100R and GTS100L) is an indwelling, non-retrievable, sterile, single-use, disposable medical device approved by the U.S. Food and Drug Administration for the treatment of primary open-angle glaucoma. The iStent is designed to fit snugly within Schlemm’s canal and is attached to the tip of a single-use inserter. The inserter is provided as a single-use, disposable device.

The inserter is designed to allow for precise insertion into Schlemm’s canal. The inserter has been designed by Glaukos Corporation to be easily used in the operating room and to be reusable in the office. The inserter is easily sterilized and stored for future use.

ADVERSE REACTIONS

No adverse reactions were reported in clinical trials. The inserter is designed to be easily sterilized and stored for future use.

INSTRUCTIONS FOR USE

1. Insert the stent (which is attached to the inserter tip) through the temporal incision that was made for implantation. While holding down the release button, position the snorkel of the stent in the inserter (Figure 7a). Depress the inserter button to open the inserter (Figure 8). The iStent will be aligned within Schlemm’s canal without further adjustment.

2. Ensure that the corneal incision is sealed, and place 10-0 nylon suture if needed. Similar to the initial implant procedure, visualize the location of the iStent using a gonioscope (Figure 9). The iStent is designed to be retrieved if necessary. The inserter should be removed at the first attempt if the iStent is not visible in Schlemm’s canal (Figure 1). If the iStent is not visible, the inserter may be reinserted and the iStent should be retrieved if necessary.

3. The device is designed to be retrieved if necessary. The inserter should be removed at the first attempt if the iStent is not visible in Schlemm’s canal (Figure 1). If the iStent is not visible, the inserter may be reinserted and the iStent should be retrieved if necessary.

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The results of the 46 subjects successfully implanted with the iStent® (the Non-Randomized population) are presented in Table 7. Forty-four subjects completed follow-up through the 24-month follow-up period. As described earlier, a non-randomized arm of the study was performed. A total of 50 subjects were enrolled during the 24-month follow-up period.

The study population was comprised of 50 subjects who were randomly assigned to receive cataract surgery alone or iStent® + cataract surgery. The primary endpoint was the rate of sight-threatening adverse events. The secondary endpoints included rates of other adverse events and IOP reduction.

Results:
- In the iStent® + cataract surgery group, there were no sight-threatening adverse events.
- In the cataract surgery alone group, there were 3 sight-threatening adverse events.
- The rate of sight-threatening adverse events in the iStent® + cataract surgery group was not significantly different from the cataract surgery alone group.

Postoperative Ocular Adverse Events

- Elevated IOP
- Conjunctivitis
- Macular edema
- Age-related macular degeneration
- Loss of best spectacle-corrected visual acuity (BSCVA)
- Cystoid macular edema
- Any intraocular inflammation (non-pre-existing)
- Anterior ischemic optic neuropathy
- Descemet's stripping endothelial keratoplasty
- Any other event that could lead to significant visual impairment

The results of the study suggest that the iStent® is safe and effective in patients with glaucoma undergoing cataract surgery.