The surgeon should perform a slit lamp gonioscopy examination prior to taking a patient
1. The following conditions may prohibit sufficient visualization of the angle required for the
2. This device may be used in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with uncontrolled IOP. The implants are provided in a preloaded configuration allowing for placement of the stent and pose a hazard.
3. The implant is provided in a preloaded configuration allowing for placement of the stent and pose a hazard.
4. In eyes with significant prior trauma
5. In patients with unmedicated IOP less than 21 mmHg nor greater than 36 mmHg
6. After complications during cataract surgery, including but not limited to, severe membrane formation, retinal detachment, retinal dialysis, retinal flap tears, secondary surgeries requiring the placement of an anterior chamber IOL and posing a hazard.
7. Look up from the iris root to find the scleral spur (white line). Then look for Schwalbe’s line. The distance between these two landmarks is the angle of the eye. Focus on the landmarks in the angle of the eye.
8. Injection of two stents:
9. Perform the following steps:
10. After the stent delivery button has been depressed for the fourth time, the injector will retrieve the last stent from the injector through the trabecular meshwork and pose a hazard.
11. The injection of two stents:
12. The safety and effectiveness of the iStent inject System was assessed through a clinical trial, 13. PIVOTAL CLINICAL TRIAL RESULTS
13. There were two (2) hypotheses for the primary effectiveness endpoint defined as ≥ 20% IOP reduction at the six-month visit. The subjects and Medical Monitor were masked to treatment assignments. Each IOP measurement was to be performed using Goldmann applanation by two observers, one of whom was masked to the treatment group. There were two (2) hypotheses for the primary effectiveness endpoint defined as ≥ 20% IOP reduction at the six-month visit. The primary safety endpoint was defined as the incidence of ocular complications associated with posterior chamber IOL implantation. There were two (2) hypotheses for the primary effectiveness endpoint defined as ≥ 20% IOP reduction at the six-month visit. The secondary efficacy endpoint was diurnal IOP reduction from baseline at Month 6.
14. The subjects and Medical Monitor were masked to treatment assignments. Each IOP measurement was to be performed using Goldmann applanation by two observers, one of whom was masked to the treatment group. The secondary efficacy endpoint was diurnal IOP reduction from baseline at Month 6.
15. Given the small number of cases in the study eye, in a patient with uncontrolled IOP, either pre- or postoperative, to undergo cataract surgery, including but not limited to, severe membrane formation, retinal detachment, retinal dialysis, retinal flap tears, secondary surgeries requiring the placement of an anterior chamber IOL and posing a hazard.
16. The secondary efficacy endpoint was diurnal IOP reduction from baseline at Month 6.
implantation were reported in the majority of cases (81.4%; n = 315). No associated clinical sequelae were noted in any cases in which a second injector was used. No difficulties with implanted with stents, 380 eyes (98.2%) were implanted with 2 stents. Four eyes (1.0%) ed as a result of excessive coughing (i.e., 0 stents implanted). Of the 386 eyes that were Operative parameters are provided for the iStent inject group and 108 Control group eyes completed the study. The outcomes provided herein are according to 386 implant population subjects who received iStent inject group and 118 subjects randomized to the control group. 219 eyes (57% of the 386 Total of 56 device-related AEs were reported during the study(coincided with the cataract surgery). The proportion of eyes experiencing an adverse event due to the device during the study (whether device-related or not) was 20.8% (118 eyes). Other AEs included 1 case (0.3%) each of iris strand and ocular irritation. AEs that occurred at ≥30 days, corneal striae, eyelash loss, iris atrophy, iris strand, medication intolerance included 1 case (0.3%) each of anterior scleritis, central retinal artery occlusion, and 7 cases (1.8%) of goniosynechiae. AEs that occurred at ≥30 days, corneal striae, eyelash loss, iris atrophy, iris strand, medication intolerance included 1 case (0.3%) each of anterior scleritis, central retinal artery occlusion, and 7 cases (1.8%) of goniosynechiae. 1 case (0.3%) each of anterior scleritis, central retinal artery occlusion, and 7 cases (1.8%) of goniosynechiae. 1 case (0.3%) each of anterior scleritis, central retinal artery occlusion, and 7 cases (1.8%) of goniosynechiae. 1 case (0.3%) each of anterior scleritis, central retinal artery occlusion, and 7 cases (1.8%) of goniosynechiae.