Figures 7c and 7d

Figure 5. PRECAUTIONS

1. The following conditions may prohibit sufficient visualization of the angle required for safe implantation and should advise the patient that this Patient ID card contains important information related to the end of this document for conditions for safe scanning.

2. Using Non-Standardized Image Analysis

3. The surgical arm is positioned posteriorly for IOP increases that may occur in the early postoperative period as a possible sequelae following cataract surgery in patients with preexisting glaucoma.

4. The sequelae of postoperative inflammation, which may cause elevated episcleral venous pressure and other type of condition that may cause elevated episcleral venous pressure and may limit iStent success.

5. The sequelae of postoperative inflammation, which may cause elevated episcleral venous pressure and other type of condition that may cause elevated episcleral venous pressure and may limit iStent success.

6. The sequelae of postoperative inflammation, which may cause elevated episcleral venous pressure and other type of condition that may cause elevated episcleral venous pressure and may limit iStent success.

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8. The sequelae of postoperative inflammation, which may cause elevated episcleral venous pressure and other type of condition that may cause elevated episcleral venous pressure and may limit iStent success.

9. The sequelae of postoperative inflammation, which may cause elevated episcleral venous pressure and other type of condition that may cause elevated episcleral venous pressure and may limit iStent success.

10. STORAGE REQUIREMENTS

The device should be stored at room temperature in range of 15º C - 45º C.

11. EXPEDIATION

If there is difficulty with injections at the desired location, try moving away from the injection site 8-9 clock (i.e. the other arm of the circle) and make sure the needle is out of the field of view (e.g. 15º position, if the last attempt at 9:00 left the eye, try at 3:00). Always re-check intraocular pressure and re-optimize the miotic’s dosage. Once the new location is chosen, move the inserter handle (to the left side of the stent) and continue the injection.

12. The sequelae of postoperative inflammation, which may cause elevated episcleral venous pressure and other type of condition that may cause elevated episcleral venous pressure and may limit iStent success.

13. The sequelae of postoperative inflammation, which may cause elevated episcleral venous pressure and other type of condition that may cause elevated episcleral venous pressure and may limit iStent success.

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Tables 6-10 present all postoperative ocular adverse events reported from Study GC-003 and Study GTS100-PAS. The overall iStent population was 444 subjects, with 293 (66%) assigned to the iStent + cataract surgery group and 151 (34%) assigned to the iStent-only group. The study included subjects previously enrolled in Glaukos Study GC-003 who would be subjected to cataract surgery during the course of the current study. The primary endpoint was the rate of iStent occlusion at 12 months, with the iStent + cataract surgery group used as the control group.

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