CLINICAL PROTOCOL

PROTOCOL NUMBER IOPCL AMD-20

Early Feasibility Study to Evaluate the Safety and Effectiveness of the IOPCL AMD MAG for Secondary Implantation in the Capsular Bag to Improve Near Vision in Subjects with Age-Related Macular Degeneration after Cataract Surgery

NCT: 04984590

December 6, 2022

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Early Feasibility Study to Evaluate the Safety and Effectiveness of the IOPCL AMD MAG for Secondary Implantation in the Capsular Bag to Improve Near Vision in Subjects with Age-Related Macular Degeneration after Cataract Surgery

Rev 5: December 6, 2022

Sponsor:
OnPoint Vision Inc.
6A Liberty, Suite 100
Aliso Viejo, CA 92656
(949) 688-0660

I have read and agree to follow the procedures as outlined in this protocol.

_____ _____

Principal Investigator Date

CONFIDENTIALITY AGREEMENT

This protocol contains confidential proprietary information with respect to products and clinical trials. I agree to hold this information in confidence and not to disclose it to any third parties for a period of three (3) years from the date of the Agreement, or until said information shall become a matter of public knowledge or until a formal written agreement for that purpose has been entered into by the parties.

_____

Print Name

_____ _____

Signature Date

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Medical Monitor: TBD

SUMMARY OF PROTOCOL REVISIONS

Revision Date	Description of Protocol Revision(s)
8/30/2021	Initial release
10/26/2021	1. Addition of Alcon SA60WF as an acceptable model for the previously implanted PCIOL 2. Update figures with AMD MAG IOPCL 3. Clarification within the Surgical Instructions for Use: a. timing of corneal markings (prior to creation of incisions) b. change in the incision size of the self-sealing incision from 2.5 mm to 2.75 mm c. use of viscoelastic to hydrolytically lift the leaflet to receive the trailing haptics d. use of viscoelastic on the surface center of the IOPCL to aid with proper closure of the cartridge flap e. complete clearing of viscoelastic at the close of the IOPCL procedure f. use of a miotic to reduce the pupil size at the close of the IOPCL procedure g. other minor clarifications
05/23/2022	4. Revised central magnification power from 11.0 diopters to 10.0.
06/03/2022	1. Addition of safety endpoints: a. Preservation of BCNVA - Proportion of eyes (<5%) that lose two or more lines of BCNVA (≥10 letters on the Sloan Near Vision Chart at 14 cm) at 12 months from baseline b. Assessment of absolute tilt of the IOPCL-AMD-MAG and the PCIOL 2. Clarification of definition of decentration 3. Addition of secondary effectiveness endpoint a. proportion of eyes achieving ≥ 4 lines improvement at 12 months from baseline 4. Addition of exploratory effectiveness endpoints: a. proportion of eyes achieving improved reading speed (at 40 cm) at 12 months from baseline defined as ≥ 2 lines/blocks of gain with a decrease in reading speed ≥ 1 minute and with overall improvement in critical point size b. proportion of eyes achieving independence from external magnifier usage at 12 months postoperatively 5. Revision to inclusion criterion #5 to include subjects with stable wet AMD without macular fluid retention or treatment within the past 12 months

	6. Addition of eligibility criterion requiring subjects to have experienced and failed high-magnification refractive correction alternatives to the AMD-MAG IOPCL 7. Addition of eligibility criteria excluding subjects with capsular instability and subjects with an anterior capsule defect caused by Nd:YAG capsulotomy 8. Clarification of testing distance for UCDVA and BCDVA 9. Clarification that assessment of IOPCL location should be performed after dilation 10. Addition of measurement of reading speed as a clinical assessment to assess improvement in reading speed 11. Addition of assessment of capsular stability preoperatively, intraoperatively and postoperatively 12. Revisions to surgical procedure including stopping rules 13. References of "IOL" revised to "PCIOL" throughout document 14. Minor clarifications
12/XX/2022	1. Revision from "contact" to "capsular" for definition of IOPCL 2. Correction to definition of a centered IOPCL AMD-MAG (i.e., maximum distance of uniform exposed area of the PCIOL outside of the IOPCL changed from "1.75 mm" to "0.75 mm") 3. Clarification to safety endpoint of incidence of adverse events based on ISO 11979-7 Grid and non-ISO-Grid 4. Addition of secondary surgical intervention safety endpoint 5. Addition of secondary effectiveness endpoints for UCNVA and BCNVA 6. Removal of inclusion criterion #4 following confirmation that Nd:YAG capsulotomy can be performed on an acrylic IOPCL. 7. Modifications to surgical technique 8. Revised exclusion criterion #4 9. Minor clarifications

Protocol IOPCL AMD-20
Early Feasibility Study to Evaluate the Safety and Effectiveness of the IOPCL AMD-MAG for Secondary Implantation in the Capsular Bag to Improve Near Vision in Subjects with Age-Related Macular Degeneration after Cataract Surgery

1. STUDY PURPOSE

To determine if the intraocular pseudophakic capsular lens (IOPCL), referred to as the IOPCL AMD-MAG, improves uncorrected near vision in subjects with age related macular degeneration when previously implanted with a Alcon SN60WF, SA60AT, or SA60WF monofocal posterior chamber intraocular lens (PCIOL) and to confirm its positional stability and adherence relative to the PCIOL.

2. STUDY DESIGN

This will be a 12-month study, in which a maximum of 10 pseudophakic subjects from three clinical sites with a diagnosis of age-related macular degeneration will be enrolled. In order to minimize bias, investigators recruited for this study will not have prior surgical experience with the IOPCL.

This study is being conducted in accordance with 21 CFR Parts 50, 54, 56 and 812.42 (U.S.C 282(j)). ISO 14155 Clinical investigation of Medical Devices for Human Subjects, ISO 11979-7, and the ethical principles laid down in the Declaration of Helsinki.

3. INTRODUCTION AND RATIONALE

The IOPCL (intraocular pseudophakic contact lens) AMD-MAG consists of a 4.5 mm diameter concave-convex optic with three opposing haptic straps, or tabs. The central 1.8 mm of the anterior surface of the optic has a power of 10 diopters. The haptic straps are designed to enter and rest within three channels created under the anterior leaflet of the capsular bag. Each channel is created with a Capsule Separator spatula. Each haptic strap or tab has a small pawl, or ridge on the bottom that is used to catch and lock on to the PCIOL optic edge. This pawl aids in both centering the IOPCL AMD -MAG on the PCIOL optic as well as allowing the haptic strap to stay securely seated while contained under the surface tension of the anterior leaflet of the capsular bag. The lens is designed to improve near vision of the AMD subject by providing magnification of 10 diopters in the central 1.8mm zone of the lens optic to improve near vision.

4. STUDY OBJECTIVE

The primary objective of this study is to determine the stability of the IOPCL-AMD-MAG to successfully adhere to a pseudophakic intraocular lens without rotation or slippage.

The secondary objective of this study is to determine if the IOPCL-AMD-MAG can improve uncorrected near visual acuity in subjects previously implanted with an Alcon SN60WF or SA60AT monofocal intraocular lens.

4.1. Safety Endpoints

- Preservation of BCDVA – Proportion of eyes (< 5%) that lose two or more lines of BCDVA (≥10 letters on the ETDRS chart) at 12 months from baseline.

- Preservation of BCNVA – Proportion of eyes (<5%) that lose two or more lines of BCNVA (≥10 letters on the Sloan Near Vision Chart at 14 cm) at 12 months from baseline.
- Incidence of secondary surgical intervention (SSI).
- Successful delivery of the IOPCL AMD-MAG as determined at all postoperative scheduled visits starting at 7-14 days post-operative.
  - No capsular tear
  - No visible damage to either the PCIOL or the IOPCL AMD - MAG
  - Uniform leaflet coverage of all IOPCL AMD - MAG haptic tabs
- Long-term adherence and positional stability
  - Gap: Minimal change in uniformity of the gap between consecutive scheduled visits at 1-2 months and later as determined by UBM measurements. Minimal change is defined as +/- 10 microns between visits is established and maintained using UBM imaging.
  - Tilt:
    - **Tilt of the PCIOL** as determined at all post-operative scheduled visits starting at 30-60 days post-operative. Minimal tilt of the PCIOL confirmed via penlight examination and defined as ≤ 10 degrees between the postoperative tilt of the PCIOL and the pre-operative tilt of the PCIOL.
    - **Tilt of the IOPCL AMD-MAG** as determined at all post-operative scheduled visits starting at 30-60 days post-operative. Minimal tilt of the IOPCL AMD-MAG (using the PCIOL as a reference point) confirmed via penlight examination and defined as ≤ 10 degrees between the post-operative tilt of the. PCIOL and the postoperative tilt of the IOPCL AMD-MAG.
  - Decentration: Decentration as determined at all post-operative scheduled visits starting at 7-14 days post-operative. Centration of the IOPCL AMD-MAG (using the PCIOL as a reference point) confirmed during slit lamp examination and defined as uniform exposed area of the PCIOL outside of the IOPCL AMD-MAG at the vertical and horizontal meridians between ≥ 0.25 mm and ≤ 0.75 mm.
- Counts and percentages for incidence of cumulative and persistent intraoperative and post-operative adverse events
- Counts and percentages for incidence of secondary surgical interventions (e.g., removal of interlenticular opacity, repositioning of IOPCL, explant of IOPCL, repositioning of PCIOL) (excluding Nd:YAG treatments for PCO).

4.2. Stopping Rules

The Sponsor or the clinical investigator can suggest suspension of the clinical trial at any time if they are in receipt of information that leads them to believe that continuing the study jeopardizes the health and welfare of the clinical trial participants. Suspension of the study will be considered if two or more consecutive severe ocular injuries or 2 or more subjects requiring explant due to visual intolerance of the device occur at any one clinical site that are related to the surgical procedure and/or IOPCL AMD-MAG device. A severe ocular injury results in a permanent impairment of a vision or permanent damage to an eye.

Examples:

- Uveitis-Glaucoma-Hyphema (UGH) Syndrome. Intraocular chafing from the IOPL/PCIOL implant leading to a spectrum of iris transillumination defects and pigmentary dispersion to microhyphemas with elevated intraocular pressure.
- Posterior capsule rupture with IOPL/PCIOL dislocation resulting in a posterior vitrectomy during the surgical procedure.

4.3. Primary Effectiveness Endpoint

Proportion of eyes (≥ 75%) able to achieve improvement of 10 letters or more of uncorrected near visual acuity (at 14 cm) at 12 months from baseline.

4.4 Secondary Effectiveness Endpoints

- Proportion of eyes (≥ 50%) able to achieve improvement of 20 letters or more of uncorrected near visual acuity (at 14 cm) at 12 months from baseline.
- Proportion of eyes (≥ 75%) able to achieve improvement of 10 letters or more when comparing uncorrected near visual acuity (UCNVA) (at 14 cm) at 12 months from baseline BCNVA (at 30 cm, wearing the appropriate preoperative distance refractive correction in addition to +3.0D add).
- Proportion of eyes (≥ 50%) able to achieve improvement of 20 letters or more when comparing uncorrected near visual acuity (UCNVA) (at 14 cm) at 12 months from baseline BCNVA (at 30 cm, wearing the appropriate preoperative distance refractive correction in addition to +3.0D add).
- Proportion of eyes (≥ 75%) able to achieve improvement of 10 letters or more when comparing best corrected near visual acuity (BCNVA) (at 14 cm) at 12 months from baseline BCNVA (at 30 cm, wearing the appropriate preoperative distance refractive correction in addition to +3.0D add).
- Proportion of eyes (≥ 50%) able to achieve improvement of 20 letters or more when comparing best corrected near visual acuity (BCNVA) (at 14 cm) at 12 months from baseline BCNVA (at 30 cm, wearing the appropriate preoperative distance refractive correction in addition to +3.0D add).

4.5 Exploratory Effectiveness Endpoints

The following exploratory effectiveness endpoints will be evaluated for eyes that achieve ≥ 20 letters of improvement in UCNVA during preoperative simulation testing.

- Proportion of eyes (≥ 75%) achieving improved reading speed (at 40 cm) at 12 months from baseline defined as ≥ 2 lines/blocks of gain with a decrease in reading speed ≥ 1 minute and with overall improvement in critical point size
- Proportion of eyes (≥ 75%) achieving independence from external magnifier usage at 12 months postoperatively.

5. SUBJECT POPULATION

A maximum of 10 pseudophakic eyes in subjects with a diagnosis of age-related macular degeneration will be implanted unilaterally with the IOPCL AMD-MAG. All ocular eligibility criteria refer to the study eye only.

5.1. Inclusion Criteria

1. Subjects aged 55 years or older.
2. Subjects who have already had cataract surgery with an Alcon SN60WF, SA60AT or SA60WF monofocal intraocular lens with a lens power between 17.0 diopters and 24.0 diopters clearly evidenced by photographic documentation by one of the following:
   - patient medical record
   - clinic chart with labeling attached
   - surgical record with labeling attached, or
   - patient identification card with make, model and serial number.
3. Subjects who have already had cataract surgery at least 6 months from the planned date of the IOPCL surgery.
4. Subjects with non-neovascular dry AMD or stable wet AMD meeting the following criteria:
   - No macular fluid retention in the past 12 months
   - No treatment within the past 12 months
   - No change in Amsler Grid test within the past 12 months
   - No subretinal fluid or macular hemorrhage confirmed by optical coherence tomography (OCT) imaging.
   - No fundoscopic changes within the past 12 months (i.e., changes in retinal pigment epithelium).
5. Subjects with best corrected distance visual acuity from 20/80 to 20/800.
6. Subjects with a preoperative manifest refraction spherical equivalent (MRSE) of +1.0D to -1.0D.
7. Subjects with ≤1.0D of corneal cylinder determined by keratometry readings.
8. Subjects who are unsatisfied with their current near vision correction provided by either spectacles or external magnifier.
9. Subjects who have experienced and failed one or more high-magnification refractive correction alternatives to the IOPCL AMD-MAG.

10. Subjects who demonstrate at least 10 letters of near visual acuity improvement with the simulation/tolerance test (using manifest refraction with +7.0D add) compared to conventional near vision testing (using manifest refraction with +3.0D add).
11. Subjects with a minimum endothelial cell count of 1800 cells/mm^2.
12. Subjects willing to abstain from pursuing any other surgical vision-correcting procedures for the duration of the study.
13. Subjects who are willing and able to complete all required postoperative visits.
14. Subjects who are able to comprehend and sign a statement of informed consent.

5.2. Exclusion Criteria

1. Subjects who have already had cataract surgery with a toric or multifocal or accommodating Intraocular Lens.
2. Subjects who have already had cataract surgery with an Alcon SN60WF, SA60AT or SA60WF monofocal intraocular lens with a power below 17.0 diopters and greater than 24.0 diopters.
3. Subjects with non-stable neovascular (wet) AMD who received treatment within the past 12-months.
4. Subjects who have had a Nd: YAG capsulotomy less than 1 month prior to the planned date of the IOPCL surgery.
5. Subjects who were treated with an PCIOL off-label.
6. Subjects who have more than 1.0D of corneal cylinder determined by keratometry readings.
7. Subjects whose continuous curvilinear capsulorhexis was less than 5mm or more than 6.0 mm in size at the time of PCIOL surgery.
8. Subjects who had cataract surgery less than 6 months from the planned date of the IOPCL surgery.
9. Subjects with anterior capsule fibrosis and phimosis that in the opinion of the investigator may confound the outcome or increase the risk to the subject.
10. Subjects with capsular instability.
11. Subjects with an anterior capsule defect.
12. Subjects with posterior capsular defect (caused by Nd:YAG capsulotomy) extending toward the equator.
13. Subjects who do not gain at least 10 letters of near visual acuity with the simulation/tolerance testing (using manifest refraction with +7.0D add) compared to conventional near vision testing (using manifest refraction with +3.0D add).
14. Subjects with a concomitant retinal or choroidal disorder other than AMD.
15. Subjects with any corneal abnormality, other than regular corneal astigmatism that in the opinion of the investigator would confound the outcome(s) of the study.
16. Subjects with clinically severe corneal dystrophy (e.g., epithelial, stromal, or endothelial dystrophy).

17. Subjects with microphthalmos.
18. Subjects with a previous retinal detachment.
19. Subjects with a recurrent severe anterior or posterior segment inflammation of unknown etiology.
20. Subjects with iris neovascularization.
21. Subjects with glaucoma.
22. Subjects with advanced visual field defects (e.g., central large scotoma where magnification would not help).
23. Subjects with a fundus not visible.
24. Subjects with aniridia.
25. Subjects with advanced optic nerve atrophy.
26. Subjects with damaged or incomplete zonules.
27. Subjects with a known history of pseudoexfoliation.
28. Subjects with acute, chronic or uncontrolled systemic or ocular disease that in the opinion of the investigator would increase the operative risk or confound the outcome(s) of the study.
29. Subjects with medications that, in the opinion of the investigator, may confound the outcome or increase the risk to the subject (tamsulosin hydrochloride (Flomax)) or other medications with similar side effects (floppy iris syndrome).
30. Subjects with cognitive impairment that may interfere with the ability to understand the potentially complex considerations underlying an informed decision on trial participation and/or interfere with the ability to neuro-adapt to this device in the postoperative period.

6. SUBJECT ENTRY

The investigator or qualified site personnel will explain the study purpose and procedures necessary to allow the subject to decide whether to give informed consent and will explain the subject's responsibilities (see Appendix 1).

The subject's willingness and ability to meet the follow-up requirements will be determined. After it has been determined that all inclusion/exclusion criteria have been met the subject will be enrolled into the study.

6.1. Outcome Simulation Testing

After informed consent has been obtained the subject will be required to participate in a "Outcome Simulation test." First, the subject's manifest refraction will be placed in a trial frame. Next, using the add power of commonly-used spectacles, a +3.0D lens will be placed into the trial frame and near visual acuity will be tested using the Sloan Near Vision Chart at 30 centimeters (11.5 inches) and at the subject's preferred reading distance (i.e., the distance at which the subject can most clearly see the chart or reading material). Then, the +3.0D lens will be exchanged for a +7.0D lens and near visual acuity will be assessed using the Sloan chart at 14 centimeters (5.5 inches) and the

subject's preferred reading distance. This will closely simulate the expected outcome after surgery and determine if he/she can tolerate the high magnification. Subjects who demonstrate at least 10 letters of near visual acuity improvement with the +7.0D lens, compared to near visual acuity achieved with the +3.0D lens, will have the option to continue with the remaining pre-operative testing or to withdraw from the study. Subjects who fail to achieve at least 10 letters of near visual acuity improvement with the simulation testing or who are not completely tolerant of their vision during the simulation testing will be exited from the study.

7. TREATMENT PLAN

Duration of Study Treatment – 12 Months (330-420 days).

All subjects will receive the investigator standard postoperative regimen for cataract surgery. The retinal status of the subject will be monitored with a co-managing retinal specialist throughout the course of the trial.

8. EYE TO BE TREATED

If both eyes are eligible for the procedure, the study eye should be chosen based on the least amount of potential risk (i.e., the study eye that has the worse degree of pathology). If the level of pathology is the same OU, the non-dominant eye will be implanted.

9. ASSESSMENT FOR CAPSULAR STABILITY

Assessment for capsular stability will be performed preoperatively, intraoperatively and postoperatively.

10. OPHTHALMIC VISCO-SURGICAL DEVICE (OVD)

ProVisc® (sodium hyaluronate) Alcon, will be used as a surgical aid when inserting the IOPCL AMD MAG.

11. POSITION OF PCIOL HAPTICS AND IOPCL INCISION LOCATION

After adequate dilation, the surgeon will determine and record the orientation and angular dimensions of the haptics of the in-place PCIOL. The surgeon will also determine the degree and angular dimensions of the anterior capsule coverage in the planned region of the tri-haptic tunnel formation. The surgeon will determine if there is adequate coverage of the anterior leaflet capsule at the edge of the underlying PCIOL where the haptics of the IOPCL will reside. Adequate coverage is defined as greater than or equal to 0.5 mm of anterior leaflet of capsule above where the haptics will reside.

These notations will be transferred to the Pre-Operative case report form to document the position of the PCIOL haptics and IOPCL incision location.

12. SURGICAL TECHNIQUE: INSERTION AND REMOVAL INSTRUCTIONS

Video recordings will be created for each subject surgery and provided to the Sponsor for future review and assessment. **Prior to recording the case, please ensure that the video equipment is in full working order**. Video recordings will be shared with the FDA**.**

Any deviations from the surgical techniques described in the following sections should be captured as protocol deviations.

The Intraocular Pseudophakic Contact Lens (IOPCL) AMD-MAG is designed to improve near vision in the pseudophakic eye with AMD. Using a novel tripod haptic design (see figure 1) placed within 3 channels created under the anterior leaflet of the capsular bag, the optic is designed to self-center, secured over the existing posterior chamber intraocular lens (PCIOL). Each haptic has a ridge that acts as a pawl on the bottom that catches and locks onto the PCIOL optic edge. This pawl aids in both centering the IOPCL on the PCIOL optic as well as securely seat the haptic while contained under the anterior leaflet of the capsular bag. The lens is 4.5mm in diameter with the 3 extending haptics arranged in an isosceles pattern to avoid interference with the haptic/optic junctions of the existing PCIOL. The apex and leading tab are marked R to identify the anterior surface of the lens and prevent inverse implantation and help guide positioning onto the existing PCIOL. When the lens is right-side up the R should be visible and properly oriented when implanting the IOPCL.

Figure 1 - IOPCL AMD-MAG

12.1. Instructions for Use

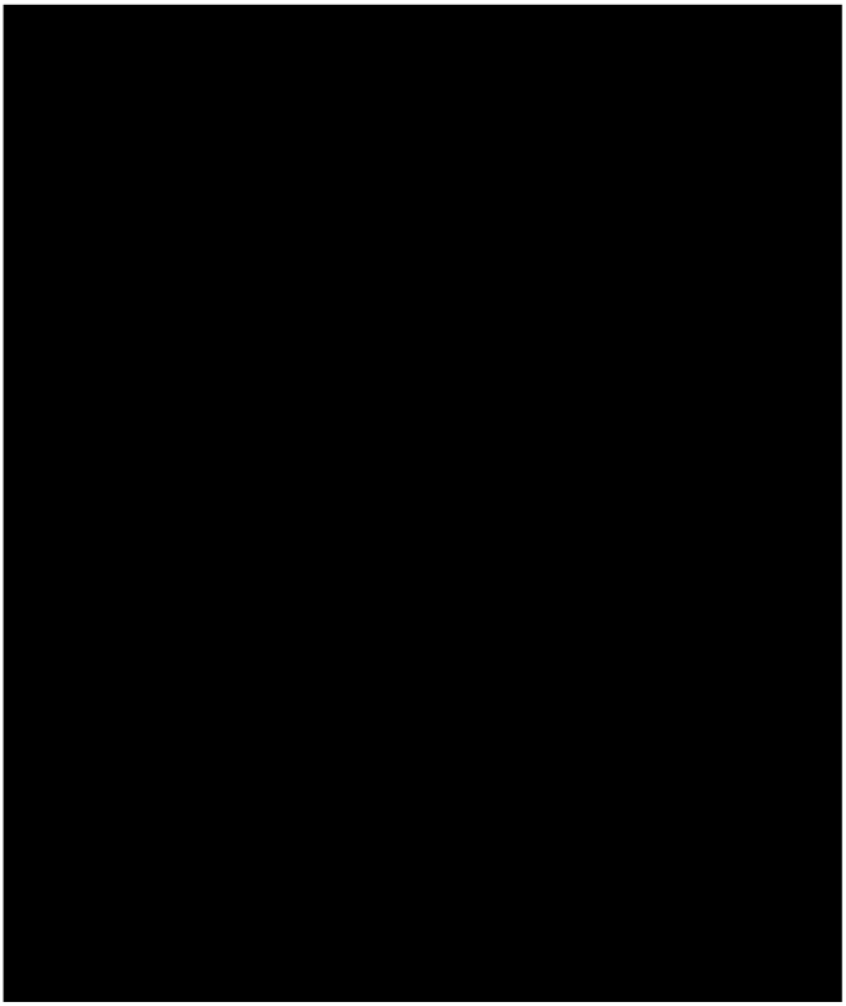
12.1.1. Access to the Anterior Chamber

1. Mark the cornea with provided cornea marker, isolating the leading haptic mark. The leading haptic mark is to be placed on a lone side of the underlying PCIOL separated by the optic-haptic junction. The projected markings are to help guide the surgeon as to where the 1.5 anterior leaflet channel and partially dissected area of the anterior leaflet will be created to receive the IOPCL AMD-MAG haptic system.

Under sterile technique create a 2.75 mm wide beveled, self-sealing incision from the clear corneal limbus into the anterior chamber directly across from the planned placement of the leading haptic (denoted with the "R" inversion mark). Construct a 1.5 mm paracentesis directly across from initial 2.75 mm incision, with option (Surgeon preference) to create an additional paracentesis in any chosen plane to aid in IOPCL AMD-MAG positioning. The IOPCL AMD-MAG should be free from interfering with the optic-haptic junctions of the already seated in-the-bag PCIOL.

Figure 2 - ALIGNMENT OF THE IOPCL AMD-MAG

IOPCL ALIGNED TO IOL
IN CONTACT VERTICALLY



12.1.2. Assessment for Capsular Stability

With ProVisc in the anterior chamber using the Capsule Separator, enter the anterior chamber through the initial 2.75 mm incision. Prior to proceeding with anterior capsule dissection, confirm that the capsule is stable. Using the capsule separator, exert gentle downward force at each quadrant of the capsule aligned with the corneal mark to confirm that pseudophakodonesis is not present and that the capsule has minimal movement. If mobility of the lens/bag complex is too great that dissection cannot be performed without significant displacement of the lens/bag complex, the procedure should be aborted to avoid further stress on the zonules that may compromise the future stability of the lens/bag complex. If dissection can be performed without undue deformation of the lens/bag complex, continue with the procedure. Once again, introduce spatula through initial 2.75 mm main incision and cross iris plane in preparation to create an approximate 1.5 mm tunnel under the anterior leaflet of the capsule at leading haptic mark.

12.1.3. Preparation of the Capsular Channels

Construct a liberal 1.5 mm size tunnel under the anterior leaflet of the capsule to house the leading haptic tab Note: The 'R' haptic is to be positioned between the two PCIOL haptics and the other two haptics on the other side between the two haptics markings, as shown in **Figure 2**. Using the lateral mark on the anterior surface of the spatula as a guide, advance the spatula beyond the edge of the PCIOL until the lateral mark is aligned with edge of the underlying PCIOL. Suggestion: Separate leading edge of anterior capsule approximately 2 mm either side of corneal marking to ease introduction of IOPCL haptic leading edge. Utilizing the paracentesis, introduce and advance the spatula across iris plane and create a sweeping dissection of anterior leaflet from the center of one corneal mark to the other. If cortical material is present, break up and remove any loose cortical material. Once again using the lateral mark on the anterior surface of the spatula as your guide, create a space approx. 2mm beyond the edge of the existing PCIOL to allow space for the tip of each IOPCL haptic to properly seat unrestricted beyond the optic edge of the existing PCIOL. To further dissect or elevate anterior leaflet from capsule, you may insert viscoelastic under the leading haptic tunnel and swept area of the anterior leaflet capsule.

12.1.4. Insertion of the IOPCL

Load the IOPCL into the LIOLI-22 injector according to the manufacturer's instructions.

CAUTION: It is important to place the IOPCL in the center of the cartridge chamber so that the haptics are well away from the edges of the flaps when they are folded closed. Otherwise, the haptics may get caught between the flaps and become torn when the plunger is pressed to advance the IOPCL AMD-MAG in the injector tip. It is also suggested that additional ProVisc be placed at the posterior entrance to the cartridge to provide a buffer between the plunger and the folded IOPCL AMD-MAG. Place additional viscoelastic on the surface center of the optic and while closing the cartridge press down on the center of the optic with IOL forceps to assure the haptics remain free of the cartridge flap. Once the cartridge is successfully closed, insert cartridge into provided slot of injector. Carefully push the plunger forward to ensure that the silicone tip correctly enters the loading chamber, while making sure not to capture one of the haptics between the plunger and the cartridge wall. Continue to push the tip until the inner spring begins to compress. Pull the plunger back a few millimeters and then push it forward again. This step ensures that the lens is advanced without restriction.

Through the previously placed 2.75 mm main cornea incision, inject the IOPCL AMD-MAG with the leading haptic forward denoted by the "R" inversion mark into the anterior chamber of the eye. Using an IOL manipulator, such as Sinskey or collar button, rotate the IOPCL AMD-MAG to line up the haptics with the previously created channels. Utilizing an IOL manipulator, introduce first the trailing haptics under the partially dissected area of the anterior leaflet assuring each haptic is seated properly and can grasp the edge of the IOL. Next, introduce the leading haptic into the previously created 1.5 mm anterior leaflet tunnel. If needed during the introduction of the haptic system, introduce a second instrument through paracentesis or the main incision to aid in lifting edge of capsule to ease the advancement of the IOPCL AMD-MAG haptic system under the anterior leaflet. After the placement of each haptic, confirm that it is beneath the anterior flap, properly seated and has captured the edge of the existing PCIOL. Finally, using light rocking motion, manipulate the IOPCL AMD-MAG to assure the tri-haptic system has a uniform grasp to

the edge of the underlying PCIOL. Confirm the capsule is stable by applying gentle pressure to all three seated haptic. If capsular stability is not confirmed, the IOPCL AMD-MAG should be removed (refer to Section 12.1.7 for removal instructions). Once stability is confirmed, perform thorough irrigation/aspiration of OVD and any displaced cortical material.

12.1.5. Ease of Handling Capsular Tissue during IOPCL implantation

The amount of difficulty handling the capsular tissue during IOPCL implantation and the operative date of the PCIOL procedure will be recorded on the operative form.

12.1.6. Removing Cellular Matter (Opacification) between the PCIOL and IOPCL

Removal of cellular matter (opacification) between the PCIOL and IOPCL will be recorded. **Prior to recording, please ensure that the video equipment is in full working order**. Video recordings will be shared with the Sponsor and FDA**.**

Using an irrigating cannula and BSS loosen the cortical/cellular material between the two lenses from the periphery, followed by removal with a coaxial/aspiration (I/A handpiece). Alternatively utilize a bi-manual I/A system with separate irrigation and aspiration handpieces. These small handpieces can be introduced through two 1.0 mm paracentesis incisions and can easily fit between the two lenses delivering irrigation from one side and aspiration from the opposite side to remove any cortical or inter-lenticular cellular material place a small amount of ProVisc® within the angle of the anterior chamber to stabilize the chamber while allowing for free flow of BSS fluid. Use a straight 27-gauge cannula on a 5cc syringe filled with BSS to vigorously irrigate the space between the two lenses. If for some reason the vigorous irrigation did not remove all the debris from the inter-lenticular space carefully release the haptic/tabs of the IOPCL closest to the location of the debris and continue to irrigate. If this approach is unsuccessful consider removing the IOPCL, irrigate the surface debris on the surface of the PCIOL and replace it with another IOPCL. If the debris attached to the surface of the PCIOL remains adhered after the final attempt to irrigate do not introduce a new IOPCL. **At the conclusion of the case, please record in detail on the CRF every and all steps taken to remove the cellular material between the two lenses.**

12.1.7. Removal of the IOPCL

The IOPCL is only to be removed for specific causes such as, but not limited to, subject intolerance, damage to the IOPCL and/or base PCIOL, and adverse events being caused by the presence of the IOPCL (e.g., pupillary block or reduced vision).

Removal of the IOPCL will be recorded. **Prior to recording, please ensure that the video equipment is in full working order**. Video recordings will be shared with the Sponsor and FDA**.**

*REMOVAL INSTRUCTIONS***:**

Re-open the initial incisions or create new access into the anterior chamber if they have healed. With ProVisc in the anterior chamber use a Sinskey hook or similar instrument to disengage the three IOPCL haptics from their respective channels. Place a small amount of ProVisc between the IOPCL and existing PCIOL to separate them apart. Using micro-forceps thru the 2.0 mm wide incision, grasp the anterior and posterior surface of the IOPCL and remove it through the incision. The IOPCL is flexible and will fold and achieve a "taco" form for removal in one piece. After explantation of the complete IOPCL, assess the lens surface of the existing PCIOL for any damage. If any damage is noticed on the existing PCIOL particularly on its lens surface, please record this on the IOPCL removal Case Report Form. Remove the remaining ProVisc, irrigate and close the wound per your normal PCIOL procedures.

Please return the removed IOPCL to the Sponsor for damage assessment.

13. ND:YAG CAPSULOTOMY AFTER IMPLANTATION OF THE PCIOL

An Nd: YAG capsulotomy **is not allowed** to treat opacity between the IOPCL and PCIOL after implanting the IOPCL. Irrigation should be performed to remove the cellular matter from the lens(es) See page 9 for irrigation instructions.

14. EXAMINATION SCHEDULE

Subjects will be examined and evaluated according to the following schedule of visits.

- Form OA – Pre-Operative
- Operative (Form OB)
- Form 1 (1 to 2 days postoperative)
- Form 2 (7-14 days postoperative)
- Form 3 (30-60 days postoperative)
- Form 4 (120-180 days postoperative)
- Form 5 (330-420 days postoperative)

14.1. Post-Explantation IOPCL Examination Schedule

Following the removal of the IOPCL subjects will be evaluated according to the following schedule of visits.

- Form 1X (1-2 days post-removal)
- Form 2X (7-14 days post-removal)
- Form 3X (30-60 days post-removal)

- Form 4X (120-180 days post-removal)
- Form 5X (330-420 days post-removal)

14.2. Unscheduled / Interim Visits

Additional visits may be scheduled as deemed necessary by the investigator, to ensure the safety and well-being of the subject.

15. CLINICAL ASSESSMENTS

All parameters will be recorded for both eyes at baseline (pre-operative). Measurements will be recorded for the study eye at postoperative and post-removal visits. See Appendix 2A schedule of visits (pre- and post-operative visits) and Appendix 2B (post-removal visits). See Appendix 3 for clinical assessment instructions.

Order of Clinical Assessments:

- Mesopic contrast sensitivity testing should be performed prior to the slit lamp examination and before any visual acuity testing that requires bright light directed at the subject (i.e., a reading lamp shined directly over the subject's shoulder onto the reading card).
- Confirmation of IOPCL location should be performed after the study eye is dilated.

Study sites are expected to implement COVID-19 pandemic safety measures in accordance with their local, state, and CDC health guidelines to ensure the health and well-being of the subjects and study staff who come in contact with the subjects.

Clinical Assessments and Timepoints

- Inclusion/exclusion criteria: Preoperative
- Medical history: Preoperative
- External magnifier usage: Preoperative, 30-60 days, 120-180 days, 330-420 days. Interim
    - Post-removal, 30-60 days, 120-180 days, 330-420 days, Interim
- Demographics: Preoperative
- Patient Informed Consent: Preoperative
- Capsulorhexis Size at the time of PCIOL surgery: Preoperative
- Position of PCIOL Haptics and Planned IOPCL Incision Location: Preoperative
- Axial Length: Preoperative
- Keratometry: Preoperative

- Mesopic and Photopic Pupil size measured by Pupillometer: Preoperative.
- Pseudophakic PCIOL power with make and model number: Preoperative.
- Simulation of expected outcome (3.0D lens over manifest refraction at 30cm and 7.0D lens over manifest refraction, at 14cm and preferred distance): Preoperative.
- Ocular Dominance: Preoperative
- Optical Coherence Tomography: Preoperative, 30-60 days, 120-180 days, 330-420 days. Interim
    - Post-removal, 30-60 days, 120-180 days, 330-420 days, Interim
- Capsular Stability: Preoperative, Operative, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- Spatial Visualization between the PCIOL and IOPCL Using UBM: 30-60 days, 120-180 days, 330-420 days, Interim.
- Recording of the IOPCL Surgical Procedure: Operative
- IOPCL Location and Confirmation of Incision Location: Operative
- IOPCL Location (following dilation): 1-2 days, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- Manifest Refraction: Preoperative, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- Add Power: Pre-Operative, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim.
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- BCDVA: Best Corrected Distance Visual Acuity (at 6m) – Preoperative, 7-14 days, 30-60 days, 120-18 days, 330-420 days, Interim
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- BCNVA: Best Corrected Near Visual Acuity (at 30 cm (preoperatively); 14 cm (postoperatively) and preferred reading distance (preoperatively and postoperatively)) – Pre-Operative, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim.
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim

- UCDVA: Uncorrected Distance Visual Acuity (at 6m)– Preoperative, 7-14 days, 30-60 days, 120-180 days, 330-420 days.
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days. Interim
- UCNVA: Uncorrected Near Visual Acuity (at 14 cm and preferred reading distance) – Preoperative, 7-14 days, 30-60 days, 120-180 days, 330-420 days
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- Central Visual Field (Amsler Grid): Preoperative
- Reading Speed (Smith-Kettlewell testing at 40 cm): Preoperative, 7-14 days, 30-60 days, 120-180 days, 330-420 days
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- Contrast Sensitivity (Mesopic): Preoperative, 7-14 days, 30-60 days, 120-180 days, 330-420 days
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- Slit Lamp Examination: Preoperative, 1-2 days, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim.
    - Post-removal, 1-2 days, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- Gonioscopy: 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- Intraocular Pressure: Preoperative, 1-2 days, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
    - Post-removal, 1-2 days, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- Dilated Fundoscopy: Preoperative, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
    - Post-removal, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim
- Specular Microscopy: Preoperative, 120-180 days, 330-420 days, Interim
    - Post-removal, 120-180 days, 330-420 days, Interim
- VFQ-25 Questionnaire: Preoperative, 30-60 days, 120-180 days, 330-420 days, Interim
    - Post-removal, 30-60 days, 120-180 days, 330-420 days, Interim
- Adverse Events and Complications: Operative, 1-2 days, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim

- Post-removal, 1-2 days, 7-14 days, 30-60 days, 120-180 days, 330-420 days, Interim

16. DEFINITION OF ADVERSE EVENTS

16.1. Serious Adverse Event (SAE)

Serious Adverse Event (SAE): An Unanticipated Adverse Device Effect associated with the device (UADE) is considered to be "serious" in any of the following categories and should be reported to OnPoint Vision Inc. OnPoint Vision Inc. within 5 working days after the investigator first learns of the event.

- Results in death
- Life-threatening
- Hospitalization greater than 24 hours
- Persistent and/or significant disability/incapacity
- Sight-threatening

16.2. Intraoperative Ocular Adverse Events

- Hyphema
- PCIOL Dislocation
- Retinal Tear
- Vitreous/Subchoroidal Hemorrhage
- Vitrectomy
- Retinal Detachment
    - Rhegmatogenous Retinal Detachment
- Ruptured Capsular Bag with or without Vitrectomy
- Ruptured or Damaged Zonules
- PCIOL Lens Dislocation from the Bag
    - Partial
    - Complete
- Excessive length of time in the eye to deliver (longer IOPCL AMD-MAG than 30 minutes)
- Failure to Implant IOPCL

16.3. Postoperative Ocular Adverse Events

- Endophthalmitis

- Toxic Anterior Segment Syndrome (TASS)
- Chronic Anterior Uveitis
- Hyphema
- Hypopyon
- Implantable Pseudophakic Contact Lens Dislocation
- Cystoid Macular Edema
    - Clinically Significant Cystoid Macular Edema with reduction in BCDVA of 20/40 or worse at Form 3 (1-2 months post op) or later
- Pupillary Block
- Mechanical Pupillary Block
- Retinal Detachment
    - Rhegmatogenous Retinal Detachment
- Malpositioned/Misaligned Optics (IOPCL not centered over PCIOL and with unequal leaflet coverage of all IOPCL haptic tabs, or IOPCL tilted away from the PCIOL and without anterior leaflet coverage)
    - Early onset: occurring prior to Form 4 visit window (i.e., < 120 days)
    - Late onset: occurring ≥ 120 days
- Unseated IOPCL haptic tabs (One or more haptic tabs not securely attached to the PCIOL)
- Lens Optical Performance
- Mechanical Failure (Tear in haptic tab)
- Vitreous Aspiration for Pupillary Block
- Corneal Stroma Edema
    - Corneal Edema with BCDVA of 20/40 or worse at Form 3 (1-2M post-op) or later
- Iritis present at 1-month or later
- Macular Edema present at 1-month or later
- Raised IOP requiring treatment
    - Raised IOP, greater than 10 mmHg above baseline or greater than or equal to 25 mmHg.
- Iris Chafing
- Iris Trauma
- Iris Transillumination Defects

- Pigment Dispersion
- Pseudophacodonesis or Evidence of Zonular Trauma/Dehiscence
- Inter-device opacification or fibrosis between the PCIOL and IOPCL
- Ruptured capsular tissue
- Patient Reported Symptoms described as severe.
- Inability to go down steps, stairs or curbs in dim light or at night due to postoperative vision
- Inability to notice objects in the periphery while walking due to postoperative vision
- Other

Note: Secondary Surgical Intervention(s) (SSI) may be necessary to resolve any of the adverse events identified above. If an SSI is conducted in the trial, the details of the SSI and corresponding reason for SSI will be documented on the SSI CRF.

Examples of Secondary Surgical Interventions

- Irrigation of IOPCL/PCIOL Interface
- IOPCL Exchange
- Reposition of the same Implantable Pseudophakic Contact Lens
- IOPCL Removal
- Iridectomy for Pupillary Block

17. ADVERSE EXPERIENCE AND COMPLICATION REPORTING

Throughout the course of the proposed study, all efforts will be made to remain alert to possible adverse experiences or untoward findings. If adverse experiences occur, the first concern will be the safety and welfare of the subject and appropriate medical intervention will be made. Any adverse experiences observed by the investigator or reported by the subjects, whether or not ascribed to the investigational procedure or device, will be recorded on the subject's adverse event case report form. A new adverse event case report form is used for each adverse event or adverse event-related visit.

Any serious adverse events (SAEs) and unanticipated adverse device events (UADE), whether ascribed to the investigational device or not, will be communicated as soon as possible to OnPoint Vision Inc. and to the IRB. These reports must be confirmed in writing within 5 working days of learning of the occurrence. Any subjects who are terminated from the study due to adverse experiences will be followed and documented until their medical outcome is determined, and a written report provided to OnPoint Vision Inc. by the investigator.

18. CONCOMITANT MEDICATIONS/THERAPY

The investigator may prescribe medications and therapy as deemed beneficial for the subject.

19. DATA COLLECTION

Data will be collected using case report forms (see Appendix 8). Completed case report forms will be scanned to the sponsor within seven days of the study visit.

19.1. Device Accountability

The Investigator will be responsible for keeping current and accurate records of the amount of Intraoperative Implantable Pseudophakic Contact Lenses (IOPCLs) received, implanted, and disposed/returned. The IOPCLs must be stored in a secure area and are to be implanted only in subjects enrolled in the study, in accordance with the conditions specified in this protocol. Accountability records will include.

- The lot numbers/serial numbers of the lenses received, the receipt date, and the quantity received.
- The names of the people who received, used, or disposed of the lenses.
- A record of each subject implanted with the lenses.
- Quantity of IOPCLs returned at the completion of enrollment.

19.2. Protocol Deviations

Protocol deviations will be grouped based on severity. Major/Important deviations are a subset of protocol deviations that might significantly affect the completeness, accuracy, and/or reliability of the study data or that might significantly affect a subject's rights, safety, or well-being. For example, important protocol deviations might include enrolling subjects in violation of key eligibility criteria designed to ensure a specific subject population or failing to collect data necessary to interpret primary endpoints, as this may compromise the scientific value of the trial. Protocol deviations will be grouped by type will be recorded.

19.3. Study Completion Procedures

19.3.1. Subject Completion

Subjects are considered to have completed the study if they have completed all follow-up examinations through 330-420 days (12 months) including post-removal examinations.

19.3.2. Subject Termination

Subjects may be terminated from the study at the discretion of the Investigator only for reasons related to the study treatment regimen that would jeopardize their health and/or welfare if they were to continue in the study. Terminated subjects will not be replaced. However, every effort will be made to follow terminated subjects for safety reasons using the appropriate case report forms until the planned end of the study period.

19.3.3. Subject Discontinuation

Subjects may be discontinued from the study for non-treatment-related reasons only when no other option is possible. Reasons for discontinuation include, but are not necessarily limited to, 1) voluntary withdrawal from the study by the subject; 2) subject has moved from the area and is determined to be lost to follow-up; 3) subject is unwilling or unable to cooperate with study requirements (non-compliance with post-operative follow-up visits, etc.).

Prior to discontinuing a subject, every effort should be made to contact the subject in an effort either to get the subject back into compliance with the protocol or to obtain as much follow-up data as possible regarding the subject's current visual status.

20. DATA REPORTING

A Case Report Form binder will be provided by the Sponsor for each subject who is enrolled in the study. The appropriate case report form will be completed and signed by the Investigator/examiner at each examination. All case report forms will be completed in a legible manner in ink. Any corrections will be made by drawing a single line through the incorrect entry and initialing and dating the change. Information transferred from the source document will be faxed to the sponsor.

All forms will be reviewed for completeness and evident recording errors will be rectified by contact with the appropriate persons at the clinical site. Corrective and preventative actions will be implemented to avoid repeat errors. Double entry routines will be used to minimize data entry errors, and computerized editing routines will be used to identify unusual data entries for verification prior to statistical analysis. Data analysis will be performed per the statistical analysis plan in Appendix 6.

21. RECORDING OF DATA AND RETENTION OF DOCUMENTS

Subject data will be documented in an anonymous fashion and the subject will be identified by the subject enrollment number. If, as an exception, it is necessary for safety or regulatory reasons to identify the subject, the Sponsor or its representative and the Investigator are bound to keep this information confidential.

The Investigator must retain essential documents indefinitely after the completion of the study, unless otherwise notified by the Sponsor. The Investigator agrees to adhere to the document retention procedures when signing the protocol Investigator statement of approval.

Essential documents include but are not limited to the following:

- IRB approvals for the study protocol, all amendments and informed consent form(s)
- IRB annual study review,
- Subject's signed informed consent form,

- Correspondence from and to the Sponsor, and
- Any other documents relevant to the conduct of the study.

22. STUDY MONITORING

OnPoint Vision Inc. personnel (or designees) will monitor all clinical studies in a manner consistent with good clinical practices (GCPs) and all applicable health authority regulations, and in accordance the study monitoring plan. Study monitoring will involve the following elements.

1. OnPoint Vision Inc. personnel (or designee) will meet with the investigator(s) prior to the initiation of the study in order to review the adequacy of the subject population, facilities, and equipment with respect to the needs of the study, and to familiarize the investigator with the study protocol.
2. OnPoint Vision Inc. personnel (or designee) will meet with the investigator(s) at the time study subjects begin to be enrolled in order to ensure that subjects are being properly selected and that study data are being correctly recorded.
3. OnPoint Vision Inc. personnel (or designee) may remotely review and audit or visit the clinical site at any time during the study to review the case report forms and verify data against medical records.
4. Interim monitoring visits and telephone consultation will occur as necessary during the course of the study to ensure the proper progress and documentation of the study findings.

Sponsor field staff under the supervision of the investigator will periodically visit investigational sites to ensure that study procedures (e.g., refractions, visual acuity measurements) are performed consistently and in compliance with protocol-specified techniques, and in doing so may come in direct contact with study subjects.
The rights and well-being of subjects are protected, and the study is being conducted in accordance with 21CFR, Parts 50, 54, 56 and 812.42 (U.S.C 282(j)). ISO 14155 (2011) Clinical investigation of Medical Devices for Human Subjects, ISO 11979-7, and applicable local regulations and the ethical principles laid down in the Declaration of Helsinki (see Appendix 4).

During the course of the study, if an Investigator is determined to be non-compliant with the study plan and/or applicable regulatory requirements, the Sponsor will take action to secure compliance. In addition, the Sponsor may terminate the Investigator's participation in the study if appropriate or the Investigator remains non-compliant despite the Sponsor's actions.

22.1. Remote Study Monitoring – COVID-19

Per *FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (May 14, 2020, updated January 27, 2021)*, remote study monitoring will be

implemented due to the COVID-19 pandemic. On-Point personnel will contact sites via email and telephone to review study procedures, trial participant status, and study progress.

Remote monitoring procedures are being implemented on a larger scale as clinical research sites or study personnel are not comfortable with allowing on-site monitoring visits due to the increased risk of infection. Additionally, travel restrictions have further restricted access to clinical sites and the ability to perform on-site monitoring visits. These expanded remote monitoring guidelines may be continued through study completion, even after the COVID-19 issues are resolved.

The goal of remote monitoring is consistent with all monitoring, in that it is to assure that the rights and safety of all subjects are protected and ensure the quality and integrity of the data.

The On-Point monitor will provide the clinical site with a list of documents requested based on queries or data pending review. These documents will be uploaded to a secure site which is HIPPA compliant. The site will upload the necessary source documents to the monitor for review. Any documents uploaded to the monitor must have all subject identifiers (e.g. subject name, initials, date of birth) redacted. No additional personnel or email addresses should be copied on this correspondence from the site.

The monitor may request documents from the Regulatory binder for review, but a full regulatory document review will be done at an on-site visit after restrictions have been lifted and monitors are allowed back into the practices.
On-Point will carefully document situations where monitors were unable to access, or had to delay monitoring of a clinical site. On-Point personnel and monitors will document protocol deviations, or other GCP non-compliance issues identified at the clinical sites and whether delayed identification was due to postponed monitoring.

Remote monitoring activities, including remote review of source documents, will be documented in the same level of detail as on-site monitoring activities, and any resulting actions to address issues identified from the remote source document review should be consistent with procedures and processes described in this monitoring plan.

23. CONFIDENTIALITY

All study data generated as a result of this study will be regarded as confidential, until appropriate analysis and review by the Sponsor or its designee and the Investigator(s) are completed. The results of the study may be published or presented by the Investigator(s) after the review by, and in consultation and agreement with, the Sponsor, and such that confidential or proprietary information is not disclosed. Prior to publication or presentation, a copy of the final text should be forwarded by the Investigator(s) to the

Sponsor, or its designee, for comment. Such comments shall aim to ensure the scientific integrity of the proposed publications and/or presentations and ensure that the data and material referring to OnPoint Vision Inc. products and activities receive fair, accurate, and reasonable presentation.

24. APPENDICES

Appendix 1 – Informed Consent Document
Appendix 2A – Schedule of Visits and Procedures
Appendix 2B – Schedule of Visits and Procedures after IOPCL AMD-MAG Removal
Appendix 3 – Clinical Methods
Appendix 4 – Declaration of Helsinki
Appendix 5 – Investigators Responsibility with Clinical Trial Agreement
Appendix 6 – Statistical Analysis Plan
Appendix 7 – VFQ-25 Questionnaire
Appendix 8 – Case Report Forms