CLINICAL PROTOCOL

PROTOCOL NUMBER CIIPCL-018

EARLY FEASIBILITY STUDY TO EVALUATE THE SAFETY AND EFFECTIVENESS OF THE ACCURASEE™ FOR SECONDARY IMPLANTATION IN THE CAPSULAR BAG TO CORRECT RESIDUAL REFRACTIVE ERRORS OF PREVIOUS CATARACT SURGERY

NCT: 05113979

APRIL 8, 2021

PROTOCOL CIIPCL-018

Early Feasibility Study to Evaluate the Safety and Effectiveness of the AccuraSee™ for Secondary Implantation in the Capsular Bag to Correct Residual Refractive Errors of Previous Cataract Surgery

Rev. 1: October 1, 2019
Rev. 2: February 14, 2020
Rev.3. August 10, 2020
Rev.4: October 12, 2020
Rev. 5: April 8, 2021

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

Protocol CIIPCL-018

Early Feasibility Study to Evaluate the Safety and Effectiveness of the AccuraSee™ for Secondary Implantation in the Capsular Bag to Correct Residual Refractive Errors of Previous Cataract Surgery

Study Purpose:

To determine if the intraocular pseudophakic contact lens (IOPCL), referred to as the AccuraSee, provides refractive correction using a plus powered lens in subjects with ocular pathology previously implanted with a Bausch and Lomb LI61AO or LI61SE monofocal posterior chamber intraocular lens (PCIOL) and to confirm its positional stability and adherence relative to the PCIOL.

Study Design:

This will be a 12-month three center study, in which a maximum of 10 pseudophakic subjects will be enrolled.

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.

1. Introduction and Rationale

The AccuraSee (intraocular pseudophakic contact lens) consists of a 4.5 mm diameter concave-convex optic with three opposing haptic straps, or tabs. 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 Cady-Soiseth 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 IOL optic edge. This pawl aids in both centering the AccuraSee on the IOL 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 fine-tune the residual refractive error of the longstanding pseudophakic eye. The lens design, position and surgical approach are intended to lessen the complication rate and overall invasive nature of today's available secondary lens implantation technologies.

2. Study Objective

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

The secondary objective of this study is to determine if the AccuraSee can successfully change refraction up to +3.0 diopters (D) in subjects previously implanted with an Bausch and Lomb LI61AO and LI61SE monofocal intraocular lens.

Safety Endpoints

- Preservation of BCDVA – Proportion of eyes (< 5%) that lose two or more lines of BCDVA from baseline.
- Successful delivery of the IOPCL as determined at 7-14 days post-operative
    - No capsular tear
    - Visualize centration between the PCIOL and IOPCL
    - No visible damage to either the PCIOL or the IOPCL
    - Uniform leaflet coverage of all IOPCL haptic tabs
- Long-term adherence and positional stability
    - Minimal Change in uniformity of the gap between 1-2 months and 4-6-months as determined by UBM measurements. Minimal change is defined as +/- 10 microns between visits is established and maintained using UBM imaging
- Characterization and incidence of cumulative and persistent intraoperative and post-operative adverse events.

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 occur at any one clinical site that are related to the surgical procedure and/or IOPCL 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 IOL/PCIOL implant leading to a spectrum of iris transillumination defects and pigmentary dispersion to microhyphemas with elevated intraocular pressure.
- Posterior capsule rupture with IOL/PCIOL dislocation resulting in a posterior vitrectomy during the surgical procedure

Primary Effectiveness Endpoint

Proportion of eyes (≥ 50%) able to achieve a stable target refraction, (manifest or autorefraction) within 0.5 D of the intended target. Stability is achieved when there is no change (±0.50 D) within two consecutive postoperative visits at 1 month or later visits.

3. Subject Population

A maximum of 10 pseudophakic eyes will be implanted unilaterally with the AccuraSee IOPCL.

3.1. Inclusion Criteria:

1. Subjects who have already had cataract surgery with a Bausch and Lomb monofocal intraocular lens model LI61A0 (with lens power from 18.0 diopters (D) to 23.0 D) or model LI61SE (with a lens power from18.0 D to 22.5 D),as clearly evidenced by photographic documentation with one of the following: (1) patient medical record, (2) clinic chart with labeling attached, (3) surgical record with labeling attached, or (4) patient identification card with make, model, power, and serial number.
2. Able to comprehend and sign a statement of informed consent.
3. Willing and able to complete all required postoperative visits.
4. Subjects who's baseline MRSE is between -0.5D and +3.0D
5. Best corrected visual acuity 20/80 or worse.
6. Subjects with ≤1.5D of corneal cylinder
7. Subjects willing to abstain from pursuing any other surgical vision-correcting procedures for the duration of the study.
8. Subject must be at least 22 years or older.

3.2. Exclusion Criteria

1. Subjects who have already had cataract surgery with a Toric or multifocal Intraocular Lens.
2. Subjects who have already had cataract surgery with a Bausch and Lomb monofocal intraocular lens model LI61A0 (with a lens power below 18.0 D and greater than 23.0 D) or model LI61SE (with a lens power below 18.0 D and greater than 22.5 D).
3. Subjects who were treated with an IOL off-label.
4. Subjects who have MRSE of less than -0.5Dand more than +3.0D
5. Subjects who have more than 1.5D of corneal cylinder
6. Subjects whose continuous curvilinear capsulorhexis was less than 5mm or more than 6.0 mm in size at the time of IOL surgery.
7. Subjects who had cataract surgery less than 6 months from the planned date of the IOPCL surgery.
8. 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.

9. 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.
10. Any corneal abnormality, other than regular corneal astigmatism that in the opinion of the investigator would confound the outcome(s) of the study.
11. Clinically severe corneal dystrophy (e.g., epithelial, stromal, or endothelial dystrophy).
12. Microphthalmos.
13. Previous retinal detachment.
14. Recurrent severe anterior or posterior segment inflammation of unknown etiology.
15. Iris neovascularization.
16. Uncontrolled glaucoma.
17. Aniridia.
18. Optic nerve atrophy.
19. Damaged or incomplete zonules.
20. Known history of pseudoexfoliation.
21. 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).

4. 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. The subject's willingness and ability to meet the follow-up requirements will be determined. Preoperative exam will be conducted after the subject provides informed consent (see Appendix 1).

After it has been determined that all inclusion/exclusion criteria have been met the subject will be enrolled into the study.

5. Treatment Plan

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

All patients will receive the investigator standard postoperative regimen for cataract surgery.

6. Lens Power Selection

All subjects will be implanted with a +3.0D IOPCL. Implanting this lens power in a subject with a baseline MRSE of -0.50D to +3.0D will give subjects a myopic refractive change allowing for an improvement in uncorrected vision at distance, intermediate, or near depending on the subject's preoperative refraction.

7. Ophthalmic Visco-surgical Device (OVD)

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

8. Position of IOL 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 IOL. 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 IOL 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.

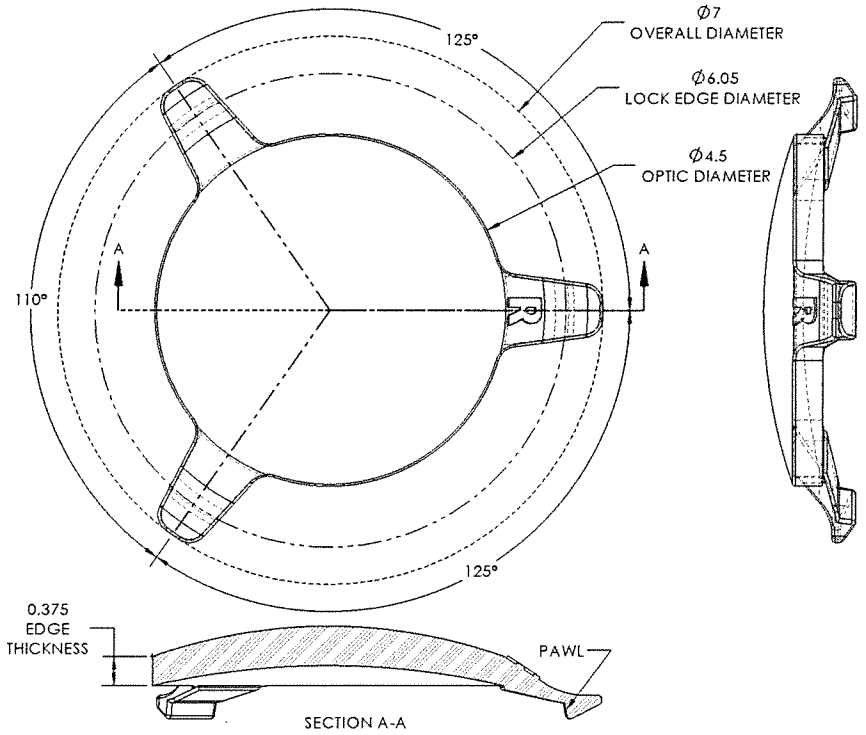
These notations will be transferred to the Pre-Operative case report form to document the position of the IOL haptics and IOPCL incision location.

9. 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.

The AccuraSee Intraocular Pseudophakic Contact Lens (IOPCL) is designed to modify the refractive error of a pseudophakic eye. 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 centered and 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 IOL 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 is 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 - AccuraSee IOPCL

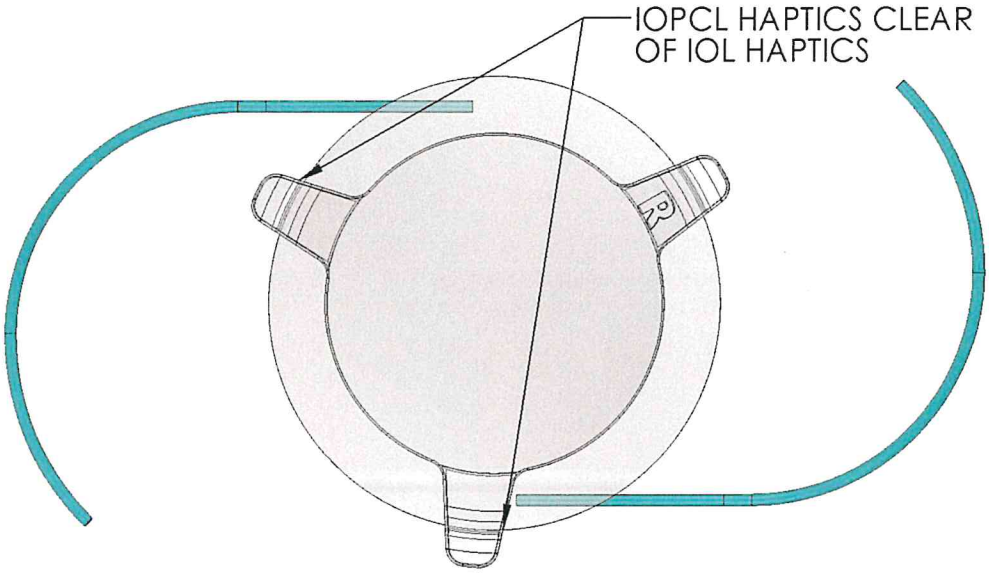


INSTRUCTIONS FOR USE

ACCESSS TO THE ANTERIOR CHAMBER

Under sterile technique create a 2.5 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 2.5 mm incision, with option (Surgeon preference) to create an additional paracentesis in any chosen plane to aid in IOPCL positioning. The IOPCL should be free from interfering with the optic-haptic junctions of the already seated in-the-bag PCIOL.

Figure 2 - ALIGNMENT OF THE AccuraSee IOPCL



PREPARATION OF THE CAPSULAR CHANNELS

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 three anterior leaflet 1.5 mm channels will be created to receive the IOPCL haptic system. With ProVisc in the anterior chamber using the Capsule Separator, create 3 channels in the appropriate positions (See figure 2) under the anterior leaflet of the capsular bag. These channels should be 1.5mm wide straddle the radial cornea mark and reach a length peripherally to just beyond the edge of the underlying IOL. The 'R' haptic is to be positioned between the two IOL haptics and the other two haptics on the other side between the two haptics, as shown. Through the initial 2.5 mm incision advance spatula across iris plane to construct a liberal 1.5 mm size tunnel to house leading haptic. Make sure to advance spatula beyond the edge of the underlying IOL about 2 mm in order to allow the leading edge of the IOPCL haptic to seat unrestricted. Suggestion: Separate leading edge of anterior capsule approximately 2mm either side of tunnel 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 one corneal mark to the other. Once again make sure you allow a 2 mm gap beyond the edge of the IOL limited to the area where the trailing haptics will be introduced and rest. If cortical material is present, break up and remove any loose cortical material. It will be necessary to create a space approx. 2.0mm beyond the edge of the existing PCIOL to allow space for the tip of each IOPCL haptic to properly seat beyond the optic edge of the existing PCIOL. In an effort to further dissect or elevate anterior leaflet from capsule, you may choose to introduce viscoelastic under leading tunnel and swept area of anterior leaflet capsule.

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 in the injector. It is also suggested that additional ProVisc be placed at the posterior entrance to the cartridge so as to provide a buffer between the plunger and the folded IOPCL. It is also suggested while closing the cartridge to press down on the center of the optic to assure the haptics remain free of the cartridge flap. 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 correctly grasped.

Inject the IOPCL with the leading haptic forward denoted by the "R" inversion mark into the anterior chamber of the eye, thru the previously placed 2.5mm cornea incision. Using angled intraocular manipulating hooks such as Sinskey or collar button, rotate the IOPCL to line up the haptics with the previously placed channels and guide the haptics into each of the 3 channels. Once distal haptics are firmly seated, grasp leading haptic with surgical tool of choice through either the 1.5 mm paracentesis incision or initial 2.5 mm incision and advance the leading haptic under the anterior leaflet into awaiting 1.5 mm tunnel. If needed introduce a second instrument through paracentesis incision to aid in lifting edge of capsule to ease the advancement of the leading haptic into created tunnel. After placing each haptic, confirm that it is beneath the anterior flap, properly seated and has captured the edge of the existing PCIOL. Ensure that there is no interference between the haptics of the pre-existing PCIOL and the IOPCL. The optic of the IOPCL should be flat and well centered to the existing PCIOL. Irrigate and aspirate all residual ProVisc and any displaced material from the anterior chamber. Once all three haptics are resting unrestricted, using light rocking motion, manipulate the IOL to assure the tri-haptic system has a uniform grasp to the edge of the underlying IOL. Finally, confirm that the IOPCL remains well centered with the haptics well secured under the anterior leaflet capsule. Hydrate and close the incision per your normal anterior chamber procedures.

REMOVING CELLULAR MATTER (OPACIFICATION) BETWEEN THE IOL AND IOPCL

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 interlenticular 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 IOL and replace it with another IOPCL. If the debris attached to the surface of the IOL 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.**

REMOVAL OF THE IOPCL

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 IOL procedures.

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

YAG CAPSULOTOMY

A 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 10 for irrigation instructions

If clinically significant PCO is observed on the posterior side of the PCIOL, treatment using standard Nd:YAG capsulotomy is allowed. Nd: YAG capsulotomy should not be performed prior to 12 weeks post IOPCL implantation.

10. 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)

10.1 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)

10.2 Unscheduled / Interim Visits

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

11. 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

- Inclusion/exclusion criteria: Preoperative
- Medical history: Preoperative
- Demographics: Preoperative
- Patient Informed Consent: Preoperative
- Measurements: Make and Model # of Equipment – Preoperative
- Axial Length & Keratometry - Preoperative
- Capsulorhexis Size at the time of IOL surgery: Preoperative
- Position of IOL Haptics and IOPCL Incision Location: Preoperative
- Mesopic and Photopic Pupil size measured by Pupilometer: Preoperative

- Predicted Post-Op Refraction: Preoperative
- Pseudophakic IOL power with make and model number: Preoperative
- 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
- UCDVA: Uncorrected Distance Visual Acuity – 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
- UCIVA: Uncorrected Intermediate Visual Acuity - 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
- UCNVA: Uncorrected Near Visual Acuity – 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
- BCDVA: Best Corrected Distance Visual Acuity – 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
- 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
- Auto-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.
- 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

- Sun Grading System: 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, 1-2 days, 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

- Quality of Vision (QoV) Questionnaire: Preoperative, 30-60 days, 120-180 days, 330-420 days.
  - 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

12. Definitions of Adverse Events

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

Intraoperative Adverse Events

- Hyphema
- IOL Dislocation
- Retinal Tear
- Vitreous/Subchoroidal Hemorrhage
- Vitrectomy

- Retinal Detachment
    - Rhegmatogenous Retinal Detachment
- Ruptured Capsular Bag with or without Vitrectomy
- Ruptured or Damaged Zonules
- IOL Lens Dislocation from the Bag
    - Partial
    - Complete
- Excessive length of time in the eye to deliver (longer AccuraSee™ than 30 minutes)
- Failure to Implant IOPCL

Postoperative 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 (1-2months post op) or later
- Pupillary Block
- Mechanical Pupillary Block
- Retinal Detachment
    - Rhegmatogenous Retinal Detachment
- Iridectomy for Pupillary Block
- Malpositioned/Misaligned Optics (IOPCL not centered over PCIOL)
    - Early[1]
    - Late[2]
- Unseated IOPCL haptic tabs (One or more haptic tabs not securely attached to the PCIOL)

- Post Nd:YAG Posterior capsulotomy event
- Lens Optical Performance
- Mechanical Failure
- 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 and to a minimum of 25 mmHg.
- Iris Chafing
- Iris Trauma and/or Damage
- Iris Transillumination Defects
- Pigment Dispersion
- Pseudophacodonesis or Evidence of Zonular Trauma/dehiscence
- Inter-device opacification or fibrosis between the PCIOL and IOPCL
- Other

[1]Early – prior to Form 4 visit window (i.e., < 120 days)

[2]Late – At 120 days or later

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/IOL Interface
- Exchange
- Reposition of the same Implantable Pseudophakic Contact Lens
- Removal

13. 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 subjects' 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. 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.

14. Concomitant Medications/Therapy

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

15. 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.

15.1. Data Collection during COVID-19 Pandemic

On March 18, 2020 the American Academy of Ophthalmology (AAO) issued a statement which included guidelines based on the recommendations from the American College of Surgeons and the CDC.

Investigational clinical sites will follow the academy guidelines for providing elective ophthalmic care. As part of these guidelines the AAO recommended protocols for scheduling and seeing patients as well as environmental cleaning and disinfection. Following these guidelines should greatly mitigate the risks for subjects who have to return to the clinic for follow-up or routine visits. Mitigating these risks will allow for reliable collection of high-quality data being collected from each clinical site following the subject visit.

15.2. 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 IOPCL's returned at the completion of enrollment.

15.3. 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.

15.4. Study Completion Procedures

15.4.1 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.

15.4.2 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.

15.4.3 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.

16. 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.

17. 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.

18. 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.

18.1 Remote Study Monitoring – COVID-19

This Remote Monitoring Plan has been developed by On-Point Vision to document the remote monitoring procedures for the CIIPCL-018 protocol that have arisen due

to the COVID-19 pandemic. Per FDA Guidance on *Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (May 14, 2020)*, On-Point Vision will be implementing remote monitoring as the COVID-19 pandemic has delayed on-site monitoring of the On-Point Vision protocol under IDE G190323. On-Point personnel are in active direct contact with 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 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 the study monitoring plan.

19. 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.

20. Appendices

Appendix 1 – Informed Consent Document
Appendix 2A – Schedule of Visits and Procedures
Appendix 2B – Schedule of Visits and Procedures after AccuraSee 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 – Quality of Vision (QoV) Questionnaire
Appendix 8 – Case Report Forms