INFORMED CONSENT DOCUMENT

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

JULY 16, 2021

RESEARCH SUBJECT INFORMATION AND INFORMED CONSENT FORM

Sponsor / Study Title:	**OnPoint Vision Inc / "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"**
Protocol Number:	**CIIPCL-018**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

NAME OF SUBJECT: _____

You have been asked to be in a research study sponsored by OnPoint Vision Inc. (hereafter referred to as the sponsor). This research study is a feasibility study of a device early in development. Information collected from this study may be used to evaluate the device design with respect to initial safety and device functionality in a small number of subjects. This information may guide future device modifications. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

The investigator is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the investigator about your health history or you may harm yourself by participating in this study.

PURPOSE OF STUDY

This is a study of an investigational device in a small number of subjects. "Investigational" means the medical device being tested is not approved by the FDA. The study is designed to gain early insights into the basic safety and device functionality. The purpose of this study is to evaluate a new intraocular lens (IOL) that attaches to your current intraocular lens that you had implanted in a previous cataract surgery. This will correct residual (unwanted) refractive errors that interfere with your best distance intermediate or near vision.

A small number (less than 10) human subjects have been implanted with this lens in this study**, therefore, there may be unforeseeable risks associated with the participation in this study.**

DESCRIPTION OF RESEARCH

The AccuraSee™, attaches to an intraocular lens (replacement for the human lens) already in place after having a "in the bag" cataract removed from the posterior chamber of your eye (space behind the colored part of your eye (iris) and in front of the lens).

Ten subjects will be enrolled into this 12-month study. This study will determine if subjects who have a diagnosis of low vision or age-related macular degeneration after cataract surgery will see improvement in at least one uncorrected (without glasses) visual range by changing the refraction of the subject. Subjects with either distance, intermediate or near, may see improvement in visual outcomes (clarity or clearness, a measure of how well a person sees) may see improvement when implanted with the AccuraSee. The AccuraSee is positioned above your intraocular lens. Three small channels approximately 1mm in length are created inside your eye to receive the three tabs on the AccuraSee. These 3 tabs hold the AccuraSee in place to prevent movement inside the capsular bag (the capsular bag holds both your intraocular lens and the AccuraSee in place).

PROCEDURE AND POSTOPERATIVE CARE

You will have to return to the study site for examination of your eyes 6 times or more: 1 time prior to surgery and 5 times after surgery over a 12-month period. Additionally, you may have to return for unscheduled visits as needed, should you encounter a complication or side effect during the study.

Both the lens and the surgical procedure are experimental. Once a cataract is removed it can never come back. However, a thin membrane (capsular bag) that holds both lenses in place can eventually become hazy and cause blurry vision. Under normal circumstances your physician would treat your IOL with a YAG laser capsulotomy to restore your clear vision. The YAG procedure is painless and takes only a few minutes to perform in the office. It involves using a laser to create a small opening in the back of the thin membrane (capsular bag) while leaving your IOL untouched.

After implantation of the AccuraSee, it is quite possible that cells inside the eye become disrupted and are sandwiched between the intraocular lens and the AccuraSee. If left untreated, these cells sandwiched between the two lenses cause hazy and blurry vision. A YAG capsulotomy cannot be performed to remove these cells. Your physician will have to take your back to the operating room and remove these trapped cells by placing a small incision in your eye and irrigating (washing away) the cells trapped between the two lenses. This method of irrigating between your IOL and AccuraSee is experimental. If this method is not successful in removing the opacity, the AccuraSee may need to be removed.

There is no data (information) available to support that the surgical procedure to implant this lens is safe. The only similarity to your cataract surgery is that your eye will be prepared in a similar fashion and that the AccuraSee will be injected into your eye using a similar injection method as when you received your current IOL.

The AccuraSee will be inserted into the eye through a small incision in the clear part of your eye and placed on top of, but not touching your current IOL inside the capsular bag. Once inside your eye 3 small channels will be created in the anterior leaflet (front) part of the capsular bag. These 3 channels will receive the 3 tabs on the lens which are designed to keep the lens in place and prevent the lens from moving. You will be lying down for the procedure. After instilling numbing drops into your eye the procedure to implant the new lens will take approximately 15 minutes. While there is no guarantee that you will not feel pain after the procedure, your doctor will instruct you on what over the counter medications you can take (i.e. Tylenol, Advil, etc.). Your eye will be patched upon leaving the surgical suite; you will need to wear the eye shield at night for 7 nights.

Each appointment will include standard ophthalmic/eye procedures; these procedures are not experimental. The exams will take approximately 30 minutes.

Participating in a clinical study is a commitment on your part to return for your scheduled visits. The information that is obtained from these visits are vital to the outcome of the study. Each subject enrolled into the study is accounted for. Missing information could impact the study integrity and credibility and could diminish the scientific value to the community. If you think that you are unable to attend all the above visits, please re-consider this commitment carefully before agreeing to participate.

COVID-19 PANDEMIC RISKS

There may be unforeseen risks due to the COVID-19 pandemic. If you agree to participate in this study, one day before your study visit to the research center, you will be contacted by phone and asked a few questions about your health status (symptoms related to COVID-19) and if you have been in contact with someone with COVID-19 within the past 14-days. If you are not experiencing COVID-19 related symptoms you will be asked to wear a facemask at all times while in the research center.

Your follow-up appointments include taking measurements of your eyes with specialized equipment. Social distancing of 3-6ft will be impossible to maintain while using the equipment. All precautions will be taken for your safety. All research staff will be wearing facemasks, keeping safe distances where possible and washing their hands on a regular basis. Equipment will be sanitized and wiped down between each subject use. If you are uncomfortable using the equipment please inform the research staff prior to starting your exam. Every effort will be made to accommodate your concerns.

It is possible that the research center may close if there is a COVID-19 related outbreak. If the clinic is closed and you are experiencing eye pain or abnormal visual symptoms, please seek emergency medical treatment right away.

If your follow-up appointment is during the closure, a research staff member will contact you to reschedule your appointment. Your appointment may fall outside of your designated timeframe. However, returning for follow-up appointments is the only way to assess the safety and effectiveness of this clinic study. Regardless, of the amount of time since your last appointment please keep your newly scheduled appointment.

If you test positive for COVID-19 do not attempt to come to the research center. Please call the research center as soon as possible and inform them that you have tested positive for COVID-19. It is important to self-quarantine for at least 14-days. Please make sure that you have provided the clinic with an emergency contact name and phone number.

If you require hospitalization for COVID-19 it could disrupt or end your clinical study participation. Upon release from hospital please inform the research center of your health status. You will be asked several questions regarding your stay in hospital and the treatment that you received. Every effort will be made to keep you in the clinical study unless you inform the research center otherwise.

POSSIBLE RISKS AND DISCOMFORTS TO IMPLANT THE ACCURASEE™

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because this device is investigational, all of its side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

As a result of the surgery and associated anesthesia, it is possible that your vision could be made worse. In some cases, complications may occur weeks, months or even years later. These and other complications may result in poor vision, total loss of vision, or even loss of the eye in rare situations. Depending upon the type of anesthesia, other risks are possible, including cardiac (heart) and respiratory (breathing) problems, and, in rare cases, death.

Not all risks associated with the use of the study device are currently known. Below is a list of reasonably foreseeable risks, but there may not be information to fully predict the frequency and severity of these risks.

Risks of surgery include, but are not limited to:

- Rupture (splitting) of the capsule that supports the intraocular lens increases your chance of a retinal detachment because the jelly like substance (vitreous) is attached to the retina. When this substance moves forward to the anterior chamber (which is located behind the cornea and in front of the colored part of your eye), it will pull on the retina which may result in a retinal detachment and increases your risk of intraocular lens dislocation, which may require intraocular lens removal and replacement with another intraocular lens
- perforation of the eye
- clouding of the front of the eye (corneal edema), which can be corrected with a corneal transplant
- swelling in the central area of the retina (called cystoid macular edema), which usually improves with time
- infection
- iris chaffing (rubbing against the iris (colored part of your eye) leading to damage and possibly causing the color to disperse (scatter) within the eye)
- damage to the cornea
- inflammation
- tissue reactions such as hematoma (solid clot of blood) or encapsulation (enclosed to a specific area)
- dislocation of exiting IOL
- detachment of the retina, an increased risk for highly nearsighted subjects, but which can usually be repaired
- uncomfortable or painful eye
- droopy eyelid
- increased astigmatism (unable to focus light evenly on the retina causing distorted images)
- glaucoma (increased pressure within the eye, causing gradual loss of sight)
- reduction in image quality
- visual disturbances (e.g., glare, halos)
- double vision
- dislocation and/or rotation of the AccuraSee

These and other complications may occur with surgery regardless of whether the AccuraSee is implanted and may result in poor vision, total loss of vision, or even loss of the eye in rare situations. Additional surgery may be required to treat these complications.

After your eye heals, its visual power may be different from what was predicted by preoperative testing. You may need to wear glasses or contact lenses after surgery to obtain your best vision. The results of surgery cannot be guaranteed.

This study will be closely monitored by the Sponsor. Discontinuation (stopping) of the study will occur if the sponsor is notified that 2 subjects who were enrolled into the study consecutively (one after the other without interruption) has experienced events that jeopardize their safety and wellbeing. Subjects already implanted with the AccuraSee will continue to be followed for the duration of the study (12 months).

If for any reason you or your doctor feels that the AccuraSee should be removed, OnPoint Vision Inc. will pay all costs associated with the surgical procedure to remove the AccuraSee.

You will be asked to return for follow-up visits through 12-months post-removal (330-420 days) at no additional charge. In addition, you will be compensated for returning for the scheduled follow-up visits.

BENEFITS

There is no guarantee that you will receive a benefit as a result of receiving the AccuraSee. Information obtained from this study may benefit future patients with the same condition and will be used to support a larger study later.

ALTERNATIVE TREATMENTS

Currently there are no surgical procedures approved to correct refractive errors after cataract surgery. Eyeglasses or contact lenses are available to correct your vision. The simplest and safest way to corrective refractive errors is to use eyeglasses. Your doctor can prescribe appropriate lenses to correct your refractive error and give you optimal vision.

COSTS

All study doctor fees, laboratory costs, and other procedures required for the study eye(s) will be provided at no cost to you.

IN CASE OF STUDY RELATED INJURY

If you are physically injured as a direct consequence of the investigational procedure, or the study plan, the medical care required to treat your injury will be provided at no cost to you, provided those costs are not reimbursable through your own health insurance. If you believe you have been hurt as a result of this study, you should contact the study doctor immediately.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

No other form of compensation is offered

PAYMENT FOR PARTICIPATION

«Compensation»

You may receive up to $1,600.00 for participating in this research study over a 12-month period. Payment will be made to you by an American Express gift card. The payment schedule is as follows:

Visit	Amount
• Pre-Operative	$200.00
• Surgery	$1,000.00
• 1-2 Days post-operative	$50.00
• 7-14 Days post-operative	$50.00
• 30-60 days post-operative	$100.00
• 120-180 days post-operative	$100.00
• 330-420 days post-operative	$100.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment after each completed visit prior to leaving the clinic.

SOURCE OF FUNDING

Funding for this research study will be provided by OnPoint Vision Inc.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- The United States Food and Drug Administration (FDA)
- Other state or federal regulatory agencies
- Advarra IRB

The Institutional Review Board (IRB), Advarra, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00051442.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study for any reason, please be aware that very little information is known about the safety of the AccuraSee. Your doctor will ask you to attend a final visit, at this visit your doctor will explain the potential side effects or terminating the study prematurely. If you are terminating the study due to relocation it may be possible for your care to be continued by another doctor participating in this research study.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- it is not in your best interest,
- you do not later consent to any future changes that may be made in the study plan,
- during the surgery, it turns out that your eye is not suitable for the implant, or
- any other reason.

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

By signing this consent form, you are not waiving any of your legal rights.

NEW FINDINGS

If there are any significant new findings learned during the course of the research study that may change your decision to be in this study, you will be told about them. You may be asked to sign a revised consent form if this occurs.

REQUIRED FOR CALIFORNIA SITES ONLY
SUBJECT'S BILL OF RIGHTS

You will be given a separate copy of the California Experimental Research Subject's Bill of Rights. If you have not received a copy of this document, please notify study staff.

AGREEMENT TO BE IN THE STUDY

If you agree to be in this study, you will be given a copy of this signed and dated consent form for your records.

I have read the information in this consent form (or it has been read to me). I have had an opportunity to have my questions answered and to think about participating. By signing this consent form, I am agreeing to enter this study.

By signing this consent form, I have not given up any of my legal rights.

_____ _____

Subject Signature Date

_____

Subject Printed Name

CONSENT DISCUSSION

I have discussed this research with the subject using language which is understandable to him or her and appropriate. I believe that I have fully informed this subject of the nature of this study, and its possible benefits and risks, and I believe the subject understood this explanation.

_____ _____

Signature of Person Conducting Informed Consent Discussion Date

_____

Printed Name of Person Conducting Informed Consent Discussion

_____ _____

Investigator Signature (if different from above) Date

_____

Investigator Printed Name

You will receive a signed and dated copy of this consent form to keep.

CONFIDENTIALITY AND THE COLLECTION, USE AND DISCLOSURE OF YOUR PERSONAL INFORMATION

This consent form also tells you about your privacy rights. If you sign this form, you will be giving your permission for the collection, use and disclosure of your personal information for the purposes of this study. Your personal health information includes your gender, date of birth (day, month and year), marital status, race, ethnic identity and your spoken language.

When possible, the information sent to the sponsor and those working for the sponsor will not identify you directly. You will be identified by a unique numerical study number. Your personal information will be used to confirm your eligibility for this study, to assess the results of this study, for purposes of safety and to meet legal and regulatory requirements. Your personal health information will be transmitted and stored using encryption technology making you unrecognizable to a third-party.

For the purposes set out above, the study doctor and study staff will disclose any new findings regarding your personal health made available to them during the study. This information will be shared with the sponsor and/or the U.S. Food and Drug Administration (FDA). The "Sponsor" includes any persons or companies contracted by the sponsor to have access to the research information during and after the study. Employees or representatives of the sponsor may be present at your study exams to ensure that study procedures are performed properly. In doing so, they will be in the exam room observing you as you undergo study procedures or exams. In addition, the U.S. Food and Drug Administration (FDA) may inspect your records.

Absolute confidentiality cannot be guaranteed because of the need to release information to these parties. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

There may be other circumstances where your information may be disclosed if required by law or for your benefit in the event of an emergency.

In the unlikely event that your personal health information is re-disclosed, you will no longer be protected by the privacy rule.

As discussed earlier in this consent, you are one of the first 10 patients who will be implanted with the AccuraSee in the United States. For this reason, your surgery will be recorded. These recordings may also be used for training purposes. You will not be identified by name.

You have access rights to your information and the possibility to correct your information according to local law and procedures. You can discuss this with your study doctor. There is no expiration for your permission. You may take away your permission to collect, use and share information about you at any time by providing reasonable notice to the study doctor. If you do this, you will not be able to stay in this study. No new information about you will be gathered after that date. However, the information about you that has already been gathered may still be used and given to others as described in this form.

Signature of Study Subject Date