Study Protocol

Clinical Investigation of the Next Generation Phaco System (VERITAS Vision System)

NCT Number: **NCT04332640**

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Clinical Investigation of the
Next Generation Phaco System (VERITAS™ Vision System)

PROTOCOL NUMBER: ALPI-101-SYST

EUDAMED number: TBD

SPONSOR: Johnson & Johnson Surgical Vision, Inc.
1700 E. St. Andrew Place
Santa Ana, CA 92705
714-247-8200

Investigator Agreement

As an Investigator, I agree to:

- Implement and conduct this study diligently and in strict compliance with this agreement; the protocol; Good Clinical Practices; 21CFR812, ISO 14155 and all other applicable FDA regulations; conditions of approval imposed by the reviewing Institutional Review Board (IRB) or Independent Ethics Committee (IEC), FDA or other regulatory authorities; and all other applicable laws and regulations.
- Supervise all testing of the device where human subjects are involved.
- Ensure that the requirements for obtaining informed consent are met.
- Obtain authorization for use/disclosure of health information (e.g., HIPAA authorization or equivalent).
- Maintain all information supplied by Johnson & Johnson Surgical Vision in confidence and, when this information is submitted to an independent IRB/IEC or any other group, it will be submitted with a designation that the material is confidential.

I have read this protocol in its entirety and I agree to all aspects.

Investigator Printed Name	Signature	Date

Sub-investigator Printed Name	Signature	Date

Acknowledged By:

Signature of Sponsor's Representative Date

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PROTOCOL CHANGE HISTORY

Version	Section(s)	Page(s)	Description of Change(s)	Rationale for Change(s)
1.0	N/A	N/A	Original	N/A
2.0	1) 1 and 4	1) 6 and 10	1) Removed restriction of OUS sites.	1) Provide more flexibility in site selection.
	2) 11	2) 24-25	2) Added description of Study-Specific Anticipated Adverse Events and updated the list of Study-Specific Anticipated Adverse Events in section 11.	2) Update the list of Study-Specific Anticipated Adverse Events and the list of Study-Specific Serious Anticipated Adverse Events.
	3) Appendix D	3) 41-44	3) Refined Appendix D “Next Generation Phaco System Performance Rating Questionnaire” and re-structured it into two parts (operative and post-operative).	3) Make the questionnaire easy to fill out.
	4) 1, 4, and 20	4) 6, 10, and 34-35	4) Modified the sample size to reflect the updated study strategy.	4) Update the sample size to collect more feedbacks from surgeons on the VERITAS Vision System.

1. SYNOPSIS

PROTOCOL: Clinical Evaluation of the Next Generation Phaco System (VERITAS™ Vision System)
Protocol Number: APLI-101-SYST

STUDY TREATMENTS: Investigational Product: The VERITAS™ Vision System. The product families include:

- VERITAS™ REMOTE CONTROL
- VERITAS™ CONSOLE
- VERITAS™ FOOTPEDAL
- VERITAS™ SWIVEL HANDPIECE
- ADVANCED FLUIDICS PACK
- ADVANCED INFUSION PACK

STUDY OBJECTIVE: The purpose of this study is to evaluate the overall clinical performance of the VERITAS™ Vision System in human subjects and to confirm the overall surgeon acceptability.

CLINICAL HYPOTHESIS: The VERITAS™ Vision System will achieve favorable surgeon acceptance and clinical performance.

OVERALL STUDY DESIGN:

Structure: Prospective, open-label clinical study.

Number of sites: Up to 3 sites.

Duration: There will be 3 scheduled visits: A Pre-Operative visit, an Operation visit (may happen on the same day as preoperative visit), and a 1-Day Post-Operative visit.

Administration: The investigators or designees will perform routine small-incision cataract surgery via phacoemulsification and use the VERITAS™ Vision system. The Investigator or designee will then complete a questionnaire regarding the clinical use of the VERITAS™ Vision system. The system log files automatically generated by the VERITAS™ Vision system after completion of each surgery will be collected.

Visit Schedule: Each subject will undergo 3 visits: Preoperative for both eyes (including informed consent, screening for study participation), Operative and 1-Day Post-Op for one eye. A questionnaire will be completed by the investigator or

designee. A typical pre-treatment visit will be approximately 60-120 minutes long, a typical operation visit will take 30-60 minutes, and a typical 1-Day post-op visit will take another 10-20 minutes.

STUDY POPULATION CHARACTERISTICS:

Condition: Presence of cataract for which phacoemulsification extraction is indicated in at least one eye.

Number of Subjects: Minimum 55 eyes and up to 150 eyes will be treated.

Inclusion Criteria (all criteria apply to each study eye):

- Minimum 22 years of age.
- Cataracts for which cataract extraction and posterior chamber IOL implantation have been planned.
- Availability, willingness, ability and sufficient cognitive awareness to comply with study requirements, examination procedures, and visits.
- Be willing to provide informed consent and authorization to disclose protected health information or equivalent documentation necessary to comply with applicable privacy laws pertaining to medical procedures in the governing countries.

Exclusion Criteria (all criteria apply to each study eye):

- Expected surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled intraocular pressure change, or significant vitreous prolapse or loss).
- Subjects with only one good eye (e.g. amblyopic condition etc.).
- Subjects with conditions associated with increased risk of zonular rupture, including capsular or zonular abnormalities that may lead to IOL decentration, including pseudoexfoliation, trauma, or posterior capsule defects.
- History or current use of alpha-1 antagonist medication (e.g., Flomax).
- Any condition which, in the Investigator's opinion, would make it unsafe (for the subject or for the study personnel) to treat the subject as part of this research study or for which cataract surgery is contraindicated.
- Pupil abnormalities (non-reactive, fixed pupils, or abnormally shaped pupils).
- Is pregnant, or is breast feeding, or intend to become pregnant during the study.
- Concurrent participation or expected participation in an interventional (i.e., surgical or pharmaceutical interventional) clinical trial within 14 days prior to study screening.

STUDY ENDPOINTS:

Primary Endpoints:

- Overall clinical performance will be evaluated based on surgeon's ratings, system log files, operative report and other medical records for the following items:
    - Rating of anterior chamber stability
    - Rating of followability
    - Rating of holdability
    - Rating of Phaco (cutting) efficiency
    - Satisfaction with usability of VERITAS™ Vision System
    - Overall satisfaction with VERITAS™ Vision System

  Note: Surgeon rating will be on a scale from 1 to 5, defined as 1 – unsatisfied, 2-somewhat unsatisfied, 3 – neither satisfied nor unsatisfied, 4 – satisfied and 5 – very satisfied. Surgeon acceptability will be considered favorable for scores of 4 and 5.

Other Endpoints:

- Effective Phaco Time (EPT)
- Ultrasonic Time (UST)
- Average Phaco Power (AVG)
- Volume of balanced salt solution (BSS) used
- Satisfaction with VERITAS™ Footpedal
- Satisfaction with VERITAS™ Swivel Handpiece
- Rating of corneal clarity at 1-day post-op
- Satisfaction with 1-day post-op clinical results of surgery with VERITAS™ Vision System
- Rate of adverse events and complications.

Note: Other endpoints will be collected from surgeon's ratings, system log files, operative report and other medical records.

STUDY VISITS AND PROCEDURES:

Inclusion and exclusion qualifications will be assessed at the preoperative visit according to the inclusion/exclusion criteria. The Informed Consent Document and Authorization for Use/Disclosure of Health Information form (HIPAA authorization or equivalent documentation necessary to comply with applicable privacy laws pertaining to medical treatment in the governing countries) must be signed by any subjects who agree to participate in the study prior to undergoing any study-specific procedures. The subjects are considered enrolled upon signing and dating the Informed Consent Form. After determination that all inclusion/exclusion criteria have been met, enrolled subjects will undergo cataract surgery with the VERITAS Vision System. Following the procedure, the investigator or designee will complete a questionnaire regarding the clinical use of the VERITAS™ Vision System for each case (**Appendix D**).

Key data collection includes system settings, surgeons' subjective rating on various aspects of the surgeries, medical complications, ocular/visual symptoms, and adverse events during the study.

A chart summary of procedures required at each visit is provided in **Appendix A**.

DATA ANALYSIS:

Clinical performance will be considered favorable for rating scores of 4 (satisfied) and above (based on a 1 [unsatisfied] – 5 [very satisfied] scale). Surgeon rating scores will be presented as proportion with associated confidence interval for scores of 4 and above for each item in the surgeon questionnaires (**Appendix D**).

Sample Size Calculation:

Minimum 55 eyes and up to 150 eyes will be treated to gain further surgeon experience with the new system.

A two-sided 95% confidence interval for an expected proportion of 0.95 using the large sample normal approximation will extend 0.058 (i.e., the precision of 5.8%) with a sample size of 55 eyes and will extend 0.035 (i.e., the precision of 3.5%) with a sample size of 150 eyes.

2. BACKGROUND/INTRODUCTION

Phacoemulsification, using ultrasound energy, has evolved to be the most efficient method for cataract extraction and cataract surgery. The current trend for phacoemulsification includes smaller incision size, higher vacuum level usage, as well as continuously evolving techniques for lowering ultrasound energy and more efficient cataract removal.

The VERITAS™ Vision System is a next generation Phacoemulsification (Phaco) system from Johnson & Johnson Surgical Vision (JJSV). It aspirates the emulsified lens out of the chamber, and provides irrigation to help maintain the depth and pressure of the chamber. The VERITAS™ Vision system sub-modes allow the surgeon to also perform Diathermy (electrical cauterization) and Vitrectomy (a cutting action).

3. CLINICAL HYPOTHESIS

The VERITAS™ Vision System will achieve favorable surgeon acceptance and clinical performance based on their responses to the key clinical performance questions listed in **Appendix D**.

4. STUDY DESIGN

This study is a prospective, open-label clinical study of the VERITAS™ Vision System.

The study will be conducted at up to three sites, with minimum 55 eyes and up to 150 eyes to be treated. The investigator or designee will perform the cataract surgery with the VERITAS™ Vision System on the subjects. The data from the system log files, the questionnaire, the operative report and other medical records will be used to assess the clinical utilization of the VERITAS™ Vision System.

JUSTIFICATION OF STUDY DESIGN:

The study is being conducted to evaluate the overall clinical performance of the VERITAS™ Vision System in human subjects and to confirm the overall surgeon acceptability.

5. ACRONYMS

The following acronyms are used throughout the document:

- ACD: Anterior Chamber Depth
- AVG: Average Phaco Power
- BCDVA: Best Corrected Distance Visual Acuity
- D: Diopters
- EPT: Effective Phaco Time
- IEC: Independent Ethics Committee
- IOP: Intraocular Pressure
- IRB: Institutional Review Board
- JJSV: Johnson & Johnson Surgical Vision
- UCDVA: Uncorrected Distance Visual Acuity
- UST: Ultrasonic Time

6. STUDY OBJECTIVES AND ENDPOINTS

The purpose of this study is to evaluate the overall clinical performance of the VERITAS™ Vision System in human subjects and to confirm the overall surgeon acceptability.

6.1 ENDPOINTS

Primary Endpoints:

- Overall clinical performance will be evaluated based on surgeon's ratings, system log files, operative report and other medical records for the following items:
    - Rating of anterior chamber stability
    - Rating of followability
    - Rating of holdability
    - Rating of Phaco (cutting) efficiency
    - Satisfaction with usability of VERITAS™ Vision System
    - Overall satisfaction with VERITAS™ Vision System

  Note: Surgeon rating will be on a scale from 1 to 5, defined as 1 – unsatisfied, 2-somewhat unsatisfied, 3 – neither satisfied nor unsatisfied, 4 – satisfied and 5 – very satisfied. Surgeon acceptability will be considered favorable for scores of 4 and 5.

Other Endpoints:

- Effective Phaco Time (EPT)
- Ultrasonic Time (UST)
- Average Phaco Power (AVG)
- Volume of balanced salt solution (BSS) used
- Satisfaction with VERITAS™ Footpedal
- Satisfaction with VERITAS™ Swivel Handpiece
- Rating of corneal clarity at 1-day post-op
- Satisfaction with 1-day post-op clinical results of surgery with VERITAS™ Vision System
- Rate of adverse events and complications.

Note: Other endpoints will be collected from surgeon's ratings, system log files, operative report and other medical records.

7. STUDY PRODUCTS

The VERITAS™ Vision System is intended to be used to perform cataract surgery by utilization of Phacoemulsification technique. VERITAS™ aspirates the emulsified lens out of the chamber, and provides irrigation to help maintain the depth and pressure of the chamber. The VERITAS™ Vision System's sub-modes allow surgeons to also perform Diathermy (electrical cauterization) and Vitrectomy (a cutting action).

A set of preprogrammed default surgical modes and settings are provided with the system. The surgeon controls the various aspects of the surgical procedure by pre-programming the system (via VERITAS™ Footpedal, remote, and/or touch screen) for the surgeons' specifications, and then using a VERITAS™ Footpedal to control the modes and power output during surgery.

The VERITAS™ Vision System is designed to be used with OPO73, Advanced Infusion (AI) and Advanced Fluidics (AF) packs. These packs are dual pump fluidic tubing pack which interfaces with both the peristaltic and the vacuum-based pump related components. Advanced Infusion (AI) pack supports both gravity-based irrigation and Gas Force Infusion (GFI), while Advanced Fluidics (AF) pack only supports gravity-based irrigation.

The VERITAS™ Vision System is also designed to be compatible with VERITAS™ Swivel Handpiece as well as the legacy Phaco Handpieces. However, VERITAS™ Swivel Handpiece is designed to be used with VERITAS™ Vision System only. The VERITAS™ Swivel Handpiece is not intended for use with JJSV's legacy Phaco systems.

The VERITAS™ Vision System supports the newly developed VERITAS™ Footpedal as well as the legacy JJSV's Foot pedals.

The VERITAS™ Vision System is designed to be used with VERITAS™ Remote Control only. It does not support legacy Remote Control.

Note: The clinical study will be performed with the VERITAS system and available, compatible accessories such as fluidics packs, handpiece, foot pedal and remote control. The components and accessories of the VERITAS system may be updated during the trial while ensuring that the system and accessories conform to the risk analysis and risk-benefit described in the protocol.

8. STUDY POPULATION

Each research subject must meet the following inclusion/exclusion criteria in order to participate in this study:

Inclusion Criteria

- Be at least 22 years old or older.
- Cataracts for which cataract extraction and posterior chamber IOL implantation have been planned.
- Availability, willingness, ability and sufficient cognitive awareness to comply with study protocol, examination procedures and visit.
- Be willing to provide informed consent and authorization to disclose protected health information or equivalent documentation necessary to comply with applicable privacy laws pertaining to medical procedures in the governing countries.

Exclusion Criteria

- Expected surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled intraocular pressure change, or significant vitreous prolapse or loss).
- Subjects with only one good eye (e.g. amblyopic condition etc.).
- Subjects with conditions associated with increased risk of zonular rupture, including capsular or zonular abnormalities that may lead to IOL decentration, including pseudoexfoliation, trauma, or posterior capsule defects.
- History or current use of alpha-1 antagonist medication (e.g., Flomax).
- Any condition which, in the Investigator's opinion, would make it unsafe (for the subject or for the study personnel) to treat the subject as part of this research study or for which cataract surgery is contraindicated.
- Pupil abnormalities (non-reactive, fixed pupils, or abnormally shaped pupils).
- Is pregnant, or is breast feeding, or intend to become pregnant during the study.

- Concurrent participation or expected participation in an interventional (i.e., surgical or pharmaceutical interventional) clinical trial within 14 days prior to study screening.

9. INVESTIGATOR SELECTION

9.1 INVESTIGATOR QUALIFICATIONS

JJSV will select the existing cataract surgeons who are licensed to practice medicine and are experienced in performing the cataract surgeries at the investigative site.

Investigators will be selected from the ophthalmologists who are experienced in performing phacoemulsification procedures(see Appendix E List of Potential Investigators and Sub-Investigators). Licensed ophthalmologists, optometrists and/or study coordinators with Good Clinical Practice (GCP) training and experience in conducting clinical trials in the fields of ophthalmology will consent subjects and perform screening as well as pre- and post-treatment testing.

The sites where this trial will be conducted are required to have adequate staff support, as well as the necessary space and instrumentation to conduct study testing.

9.2 INVESTIGATOR OBLIGATIONS

Investigators are required to fulfill the following obligations:

- Conduct the study in accordance with the relevant and current protocol. Investigator will only make changes to a protocol after notifying and obtaining approval from JJSV, the FDA or other governing agencies, and the IRB/IEC except when necessary to protect the safety, rights or welfare of subjects.
- Personally conduct and supervise the study.
- Maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.
- Be responsible for protecting the rights, safety and welfare of subjects under the investigator's care, with particular focus on assuring subjects are not improperly influenced or coerced toward participation.
- Be responsible for the control and documentation of the devices under investigation.
- Inform subjects that the device(s) are being used for investigational purposes and that requirements relating to obtaining informed consent and IRB/IEC approval are met according to 21CFR50, 21CFR56, 21CFR812 and all other applicable laws and regulations.
- Maintain confidentiality as required by HIPAA or similar laws and regulations.
- Shall not obtain written informed consent from any subject to participate or allow any subject to participate before obtaining IRB/IEC approval.
- Document in each subject's case history that informed consent was obtained prior to participation in the study as required by 21CFR812.

- Report to JJSV and the reviewing IRB/IEC any adverse experiences that occur during the study in accordance with applicable laws and regulations.
- Maintain adequate and accurate records in accordance with applicable laws and regulations and make available all study documents and subject medical records for inspection by either JJSV, duly authorized regulatory agencies (e.g., FDA) and/or the IRB/IEC.
- Submit progress reports on the investigation to JJSV and the reviewing IRB/IEC at regular intervals, but no less often than yearly as required by 21CFR812.150.
- Ensure the IRB/IEC that is responsible for initial and continuing review of the study complies with applicable laws and regulations
- Report all changes in research activity and all unanticipated problems involving risks to subjects to the IRB/IEC.
- Supervise and permit investigational device use and disposition in accordance with applicable regulations and protocol requirements. Upon completion of enrollment or termination of the study or the investigator's part of the study, or at JJSV's request, return to JJSV any remaining supply of the investigational device.
- Provide sufficient accurate financial information to JJSV to allow JJSV to submit complete and accurate certification or disclosure statements as required by 21CFR54. Promptly update this information if any relevant changes occur during the course of the investigation or for up to one year following completion of the study
- Comply with all other obligations of clinical investigators and requirements according to all applicable FDA regulations (e.g., 21CFR812), all other applicable laws and regulations, and all conditions of approval imposed by the reviewing IRB/IEC, the FDA and the regulatory agency of the country in which the study is being conducted.
- Ensure that all associates, colleagues and employees assisting in the conduct of the study are adequately informed about the protocol, the investigational device, their study-related duties and functions and agree to fulfill their obligations in meeting the above commitments.

Investigators shall provide adequate time and resources to conduct and report on the study. The Investigator, or delegate, shall notify JJSV of any change in the conduct of the study including changes in study personnel assigned to the study project, location of the investigational device(s), or maintenance of study records, etc.

9.3 INVESTIGATOR APPROVAL

It is the responsibility of the investigator to obtain prospective approval of the study protocol, protocol amendments or changes, informed consent forms and other relevant documents (e.g., advertisements) from the IRB/IEC. All correspondence with the IRB/IEC should be retained in the Investigator Study Files/Notebook. Copies of IRB/IEC submissions and approvals should be forwarded to JJSV. Study sites will obtain IRB/IEC approvals and fulfill any other site-specific and/or region-specific regulatory requirements. The investigator is required to report to JJSV within five working days any withdrawal of approval by the reviewing IRB/IEC for his/her participation in the investigation.

Prior to the start of subject enrollment, the following documents must be approved:

- Confidentiality Agreement
- Clinical Trial Agreement
- Investigator Agreement/Protocol Signature page
- Clinical Investigator Brochure Signature page
- Financial Disclosure form
- Signed and dated copy of investigator's current curriculum vitae
- Copy of the investigator's current medical license (as available per country)

By signing the study documents, the investigator agrees to conduct this study according to the obligations above and all other applicable regulatory and legal requirements.

9.4 INVESTIGATOR INFORMATION

Information on the principal investigator at each investigative site, the coordinating investigator, the address details for each investigative site and the emergency contact details for the principal investigator of each site are listed in a separate document - Study Investigator Information.

10. EXPERIMENTAL PLAN

10.1 OVERVIEW

This study will be conducted in accordance with, the Declaration of Helsinki, ISO 14155:2011 and all other applicable laws and regulations. The study will not begin until regulatory and IRB/IEC approvals have been obtained.

This study will be a prospective, open-label clinical investigation. Minimum 55 eyes and up to 150 eyes are expected to be treated.

Key operative data include system settings, surgeons' subjective rating on various aspects of the surgeries, system log files and reports, other medical records, medical complications, and adverse events during the study.

10.2 VISIT SCHEDULE

There will be three study visits (Preoperative, operative and 1-2 days postoperative). The study visit schedule for all study subjects is outlined in **Table 1**. Unscheduled visits may be conducted as necessary at the discretion of the investigator for medically indicated follow-up.

Table 1: Visit Schedule

NAME OF VISIT	VISIT	VISIT WINDOW
1	Preoperative	Within 45 days prior to surgery
2	Operative	Day of surgery
3	1-Day Post-Op	1-2 days postoperative

10.3 PROCEDURES

The procedures in the Pre-Op visit include Informed Consent as well as preoperative exams. The procedures in the Operative Visit include cataract surgery with the VERITAS™ Vision System and completion of the Questionnaire. The procedures in the 1-Day Post-Op visit include the UCDVA, slit lamp and other exams.

Preoperative Procedures

The Investigator or designee identifies potential study participants by reviewing medical records of subjects. Potential study participants are scheduled for the study visits.

Informed Consent

At the visit, the Investigator or designee conducts the informed consent discussion and explains the study purpose, procedures, benefits, risks, discomforts, precautions and subject responsibilities to the potential study participant. The Investigator may provide written delegation of authority to a trained and qualified study staff member (e.g., study coordinator, technician) to conduct the consent discussion; however, the Investigator should be available to answer the potential participant's questions, as needed.

Once the Investigator or designee has answered all the potential participant's questions to his/her satisfaction and the potential study participant has voluntarily agreed to participate in the study, written informed consent is obtained using the IRB/IEC-approved informed consent document. The subject and the person conducting the consent discussion (Investigator or designee) print their names, sign and date the consent. If the subject is unable to read, the consent document can be read to the subject in front of an impartial witness, who also prints his/her name, signs and dates the consent.

All subjects enrolled in the study must sign the current IRB/IEC-approved informed consent document. The informed consent must be signed before any study-specific examinations are performed, and this must be documented in the source documents. An authorization for use/disclosure of health information form (HIPAA authorization) or similar medical measurement privacy law documentation must also be signed.

The Investigator maintains the signed informed consent document and the signed authorization form as a permanent part of the subject's medical records and provides a signed copy of the consent to the subject. The Investigator or designee documents in the medical records that informed consent was obtained prior to any study-specific procedures and a copy of the signed consent was given to the subject.

Potential participants who are approached with the informed consent document will be documented on the Subject Accountability Log. A subject who does not meet the eligibility criteria or who chooses to discontinue study participation at any time is documented on the Subject Accountability Log as a Screen Failure or Exited Subject along with the reason. All subjects who sign the informed consent document are assigned a subject identifier.

All preoperative testing for the study must be completed within 45 days prior to surgery. Data from routine (non-study-specific) preoperative cataract examinations performed prior to the informed consent process may be included, provided these tests are conducted no more than 45 days prior to surgery and the test date(s) are documented on the preoperative Case Report Form (CRF). If a test/exam is required by the protocol but is not part of the routine testing the investigator performs for the cataract evaluation, that test/exam is considered to be study-specific and is not to be done until after the informed consent form has been signed by the subject. Following the informed consent process, completion of the preoperative study exam and determination that the subject meets all of the required entrance criteria, the subject may be scheduled for surgery.

Preoperative testing to be performed for each eye includes the following:

Medical and Ocular History

To determine the presence of any systemic or ophthalmic factors that may affect the subject's eligibility based on the study inclusion and exclusion criteria in **Section 8**, the Investigator or designee obtain the subject's medical and ophthalmic history at the visit, including assessment of:

1) demographic information (age, gender, race/ethnicity);
2) ophthalmic conditions and medications;
3) history of ocular surgery, ocular injury, ocular infection, ocular inflammation, ocular allergy, eyelid abnormality, or ocular surface abnormality;
4) pregnant and breastfeeding conditions, if applicable;
5) recent participation in another ophthalmic clinical trial;
6) employment or relationship with any employee at the clinical study site.

Concomitant Medications (OCULAR/NON-OCULAR)

Any ocular or non-ocular medication the subject is taking should be recorded in the source documents.

Adverse Events

Subjects should be assessed at each visit for occurrence of and/or change in status of any adverse events, particularly serious and/or device-related events. See Section 11.0 for further information.

Ocular Symptoms (non-directed; spontaneous)

Subjective ocular symptoms are to be assessed at the preoperative visit by asking “Are you having any difficulties with your eyes/vision?” Subjects should not be prompted for specific responses; however, if a subject reports halos, night glare or starbursts, the level of severity should be determined (mild, moderate or severe).

Biomicroscopic Slit-Lamp Exam

A biomicroscopic slit-lamp exam must be performed at the study visit to determine if the subject meets inclusion/exclusion criteria. The Investigator or designee evaluates the eyelids, palpebral and bulbar conjunctiva, cornea, anterior chamber, iris, lens and other parts of eye using a slit lamp biomicroscope. The Investigator or designee assesses the findings for the presence of any medical findings.

Distance Visual Acuity Testing

Monocular uncorrected distance visual acuity (UCDVA) is to be measured for each eye using an ETDRS chart or per the site’s standard of care.

Intraocular Pressure (IOP)

Intraocular pressure (IOP) is to be measured for each eye using the investigator’s usual methods (e.g., Goldmann applanation or tonopen). It is recommended that the same methods be used for all study subjects at the site for the duration of the study.

Anterior Chamber Depth (ACD)

Anterior Chamber Depth is to be measured for each eye using the investigator’s usual methods.

Corneal Densitometry

The corneal densitometry is to be measured through Pentacam, Galilei G6 or other corneal densitometry system at the designated visits. The same corneal densitometry device is to be used throughout the duration of the study.

Additional Preoperative information to be collected:

- Cataract type and density for each eye
- Planned surgery date

Operative Procedures

The investigator should use his or her standard, small-incision, cataract extraction surgical technique. Each surgeon will be trained on the use of the VERITAS™ Vision System. The surgeries are to be video recorded through surgical microscope and digital video recorder.

Clinical Assessment

The following variables will be recorded as quantitative data to assess system clinical performance during the phacoemulsification procedure. These data will be used to understand optimal system settings.

- Effective Phaco Time (EPT)
- Ultrasonic Time (UST)
- Average Phaco Power (AVG)
- Volume of balanced salt solution (BSS) used: A member of surgery team shall note the volume of BSS left in the BSS bottle/bag before and after each surgery, to assess the volume used for each case.

Questionnaire

The surgeon will complete a questionnaire (the first 15 questions within the questionnaire) related to the use of the investigational study device for each subject following surgery (**Appendix D**).

Biomicroscopic Slit-Lamp Exam

A biomicroscopic slit-lamp exam is be performed after surgery completion at the same day of operative visit to assess corneal clarity and determine the presence or absence of any medical or lens findings, complications or adverse events.

Additional operative information collected includes:

- Date of surgery
- Operative eye
- Product deficiencies / complaints
- Operative report and system log files.
- Device deficiencies/Complications/Adverse events
- Ocular medications

Postoperative Procedures

Postoperatively, subjects will be examined according to the schedule in Section 10.2, Visit Schedule. After each surgery, the treated eye will be examined 1 day postoperatively (1-2 days). The postoperative case report form will include the following information (**Appendix A**):

Distance Visual Acuity Testing

Monocular UCDVA and best corrected distance visual acuity (BCDVA) will be measured for all subjects postoperatively using an ETDRS chart or per site's standard of care.

Biomicroscopic Slit-Lamp Exam

A biomicroscopic slit-lamp exam must be performed at the postoperative visit to determine the presence or absence of any medical or lens findings, complications or adverse events.

Findings of aqueous cells and flare, corneal edema, corneal clarity, posterior capsule striae (wrinkles), and posterior capsule opacification are to be rated using standardized grading scales of 0 to +4 (0 = none, +4 = severe) during the slit lamp biomicroscopy. The specific grading scales are provided in **Appendix C**.

Intraocular Pressure (IOP)

Intraocular pressure (IOP) is to be measured using the investigator's usual methods (e.g., Goldmann applanation or tonopen).

Anterior Chamber Depth (ACD)

Anterior Chamber Depth is to be measured using the investigator's usual methods.

Corneal Densitometry

The corneal densitometry is to be measured through Pentacam or Galilei G6 at the designated visit. The same corneal densitometry device is to be used throughout the duration of the study.

Ocular Symptoms (non-directed; spontaneous)

Subjective ocular symptoms are to be assessed at the postoperative visit by asking "Are you having any difficulties with your eyes/vision?" Subjects should not be prompted for specific responses; however, if a subject reports halos, night glare or starbursts, the level of severity should be determined (mild, moderate or severe).

Questionnaire

The surgeon will complete the last 2 questions within the questionnaire related to the use of the investigational study device for each subject at 1-Day postoperative visit (**Appendix D**).

Concomitant Medications

Postoperative medications should be used as is customary for each investigator and recorded in the source document for each subject. Medications will be recorded on each postoperative case report form as applicable.

Complications

Any postoperative complications must be reported via a case report form.

Adverse Events / Device deficiencies / Complications

Subjects should be assessed at the visit for occurrence of and/or change in status of any adverse events, particularly serious and/or device-related events, as well as any device deficiencies / complications. See Section 11.0 for further information.

10.4 VERITAS™ VISION SYSTEM SUPPLY

For all the study subjects, the VERITAS™ Vision System will be supplied by JJSV prior to the first study treatment. At the completion of all study treatments, the VERITAS™ Vision System will be shipped back to JJSV following the final accountability by a JJSV Study Monitor. At all times, the storage, access and use of the VERITAS™ Vision System must be controlled.

10.5 EXIT OF SUBJECTS

An Exit Case Report Form will be completed for all subjects, either when they complete the study or if they exit early.

It is the responsibility of the investigator to provide complete follow-up data to JJSV for each subject, and every attempt should be made to gather that complete follow-up data for all subjects enrolled as missing data can have a negative effect on the study results.

A subject will be considered a “screen failure” if he/she does not meet the inclusion/exclusion criteria or if consent is withdrawn prior to cataract surgery.

If a subject is exited early from the study, the investigator or designee will complete an Exit Case Report Form indicating the reason for study exit. In the event of any serious adverse event, the subject may be exited from the study; however, efforts must be made by the investigator to follow the subject until resolution of the adverse event.

Following study completion or early exit, all study subjects are to be instructed to undergo regular eye examinations at least yearly and to return to their doctor if any eye complications are experienced in the interim.

10.6 UNSCHEDULED VISITS

During the study period or immediately after (within 1-week), if a non-protocol-required visit is done for the purpose of medically indicated follow-up for a study eye, data from this visit should be reported using the Unscheduled Visit CRF. The need for

unscheduled visits is at the investigator's discretion. Specific examinations to be performed at unscheduled visits are also at the discretion of the investigator (based on the reason for the unscheduled visit) and data are to be recorded in the appropriate section of the case report form.

10.7 PROTOCOL DEVIATIONS

Any departure from the protocol procedures represents a protocol deviation. Protocol deviations may be subject-based (e.g., inclusion/exclusion criteria, informed consent deviation, etc.) or procedural-based (e.g., out-of-interval visits, non-compliance with testing procedures, etc.). All protocol deviations will be documented in CTMS system. Any deviation made to protect the life or physical wellbeing of a subject in an emergency as well as any use of the investigational device without obtaining informed consent must be reported to JJSV within 5 working days. Protocol deviations will be monitored by JJSV, and if the non-compliance is persistent or egregious, JJSV may take action, including but not limited to termination of the investigator's participation in the study. The investigator is also responsible for informing the reviewing IRB/IEC of instances of protocol non-compliance in accordance with the IRB/IEC requirements.

11. ADVERSE EVENTS AND PRODUCT COMPLAINTS

11.1 DEFINITIONS

Adverse Event (AE)

An adverse event is defined (following ISO 14155) as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the study device.

Serious Adverse Event (SAE)

An adverse event is considered serious (following ISO 14155) if it is an untoward occurrence which may or may not be related to use of the study device that

- is sight- or life-threatening,
- results in death,
- requires inpatient hospitalization or prolongation of hospitalization (a planned hospitalization for a pre-existing condition without a serious deterioration in health is not considered a serious adverse event),
- results in permanent impairment of a body structure or body function,
- necessitates medical or surgical intervention to prevent permanent impairment to a body structure or function, or
- results in fetal distress, fetal death or a congenital abnormality or birth defect

Device-Related Adverse Event/Adverse Device Effect (ADE)

A device-related adverse event is defined as any adverse even that is believed to be definitely, probably or possibly related to the study device. A device-related event is also considered an adverse device effect (ADE; following ISO 14155) resulting from the use of the study device that may result from user error, insufficiencies or inadequacies in the

instructions for use, deployment, implantation, installation, operation of any malfunction of the device.

Study-Specific Anticipated Adverse Events

The study specific anticipated AEs are listed below and will be classified as AE or SAE dependent upon its occurrence and severity during the course of the study:

- Worsening of vision compared to baseline
- Sub-conjunctival Hemorrhage
- Loss of corneal clarity
- Inflammation that requires additional intervention (e.g. additional or increase in topical steroids outside of the normal post-operative regimen)
- Infections
- Retinal detachment
- Pupil changes
- Glaucoma
- Corneal burn
- Eye contamination (such as endophthalmitis)
- Subject or user injury (such as pinch, cut, bruise)
- Posterior capsular tear (can lead to vitreous traction, vitreous loss, and/or posterior dislocation of the cataractous lens)
- Anterior capsular tear (can lead to Intraocular lens (IOL) unable to be placed in capsular bag)
- Significant endothelial cell loss
- Electrical shock
- Burn (second degree)
- Laceration
- Irregular pupil or iris damage
- Vitreous Wick Syndrome

Study-Specific Serious Anticipated Adverse Events

The following is a list including, but not limited to, ocular adverse events that are anticipated and must be reported to JJSV for this study. Any events that are unlikely but anticipated (i.e., endophthalmitis) will be reported to the FDA and/or other appropriate regulatory agencies.

- Endophthalmitis/Intraocular infection
- Hypopyon
- Hyphema
- Cystoid macular edema
- Pupillary block
- Retinal detachment/tear

- Persistent iritis
- Raised IOP requiring treatment
- Toxic anterior segment syndrome (TASS)

Unanticipated Adverse Device Effect (UADE)/Unanticipated Serious Adverse Device Effect (USADE)

Any UADE (USA 21CFR 812.3(s)) or USADE (ISO 14155) is defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan (i.e., this protocol), application (including a supplementary plan or application), or risk assessment, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

11.2 PRODUCT COMPLAINT/DEVICE DEFICIENCY DEFINITION

A product complaint/device deficiency is defined (21 CFR 820.3(b) and ISO 14155) as any alleged deficiency related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device. This may include malfunctions, use error and inadequacies in labeling. Product complaints can pertain to any marketed JJSV device being used in the study. The investigator is to assess whether the deficiency could have led to a serious adverse event without suitable action or intervention or under less fortunate circumstances.

11.3 ADVERSE EVENT AND COMPLAINT REPORTING REQUIREMENTS

All adverse events and any complaint encountered using any JJSV product, regardless of severity and whether or not attributed to the study device(s), are to be reported to JJSV and recorded on the case report form corresponding to the visit during which awareness of the event occurred (see **Appendix E**). Adverse events are also to be reported to the reviewing IRB/IEC as per the IRB/IEC's reporting requirements. If required, adverse events will be reported to the appropriate regulatory agencies according to all applicable laws and regulations.

Reporting of adverse events shall follow ISO 14155 and country-specific guidelines, of which the shortest/strictest timeline requirement for reporting adverse events will be followed. General guidelines are provided below:

Adverse Event Reporting

An adverse event that is not serious or device-related is to be reported to JJSV in a timely manner. Notification of non-serious and non-device related adverse events will occur by recording events on the CRF when noted. Such adverse events are also to be reported to the reviewing IRB/IEC per their reporting requirements.

Complaints/Device Deficiency Reporting

A general product complaint or device deficiency is to be reported to JJSV in a timely manner. Notification of complaints/device deficiencies will occur by either recording complaints on the CRF when the complaint occurred (e.g. operative form) or by a phone call to the Sponsor. Any device deficiency that could have led to a serious adverse event without suitable action or intervention, or under less fortunate circumstances, must be reported to the sponsor immediately (no later than 24 hours after detection). Device deficiencies that could have led to a serious adverse event should also be reported to the investigator's IRB/IEC per their reporting requirements.

Serious and/or Device-Related Adverse Event Reporting

Serious and/or device related events (ADEs) are to be documented using the Serious Adverse Event/Adverse Device Effect (SAE/ADE) CRF. In the event of a serious adverse event (SAE), which may or may not be related to use of the study device, JJSV must be notified immediately (no later than 24 hours after detection). Any SAE is to be reported by phone (and/or email) and by submitting the completed SAE/ADE CRF. Any SAE or device-related AE should also be reported to the investigator's IRB/IEC per their reporting requirements.

Unanticipated Adverse Device Effect (UADE)/Unanticipated Serious Adverse Device Effect (USADE) Reporting

If during the study, a serious adverse event occurs that may reasonably be regarded as device-related and was not previously expected in nature, severity, or degree of incidence, the investigator is to report the UADE/USADE to JJSV within 24 hours, and to the investigator's IRB/IEC as soon as possible (and no later than 10 working days after learning of the event for sites in the USA as required by 21CFR812).

11.4 CAUSAL RELATIONSHIP

The investigator should always be alert to adverse events that may be related to the study device or the use of the study device (i.e., the procedure specific to the initial application of the device). An attempt should be made in every case to determine the causality of the event. The following definitions are to be used as guidelines in determining the relationship between the event and the study device and/or use of the device.

Definitely related:	If the event is associated with the device and/or the use of the device beyond a reasonable doubt, a causal relationship exists between the adverse event and the device and/or the use of the study device.
Probably related:	There is a reasonable possibility of a causal relationship between the adverse event and the device and/or the use of the study device and/or the adverse event cannot be reasonably explained by another cause.
Possibly related:	The adverse event has not been determined to be related to the device or the use of the device, but no other cause has been

identified and the device and/or the use of the study device cannot be ruled out as a possible cause.

Unlikely to be related: The possibility of a potential causal relationship between adverse event and the device and/or the use of the device could exist, but the adverse event can be reasonably explained by another cause.

Not related: There is no possibility of a causal relationship between the adverse event and the device and/or the use of the study device and/or the adverse event can be attributed to another cause.

If an adverse event is believed to be definitely, probably or possibly related to the study device and/or the use of the device, the event will be considered related to the study device and/or the use of the device.

11.5 ADVERSE EVENT FOLLOW-UP

For every adverse event, appropriate measures should be undertaken to treat and/or monitor the subject until resolution occurs. Obtain and maintain in the subject's files all pertinent medical data relating to the event including the subject's medical records and medical reports and/or judgments from colleagues or outside specialists who assisted in the measurements of the subject. The investigator should keep JJSV closely informed as to the outcome of serious and/or device-related adverse events, thereby allowing JJSV to comply with the appropriate regulatory reporting requirements. A SAE/ADE Follow-up CRF should be completed each time the subject returns to the investigator for follow-up of serious and/or device-related adverse event until resolution of the event. Any subject who is exited from the study due to a serious and/or device-related adverse event or prior to resolution of such an event will be followed until the outcome is determined.

12. PROTOCOL CHANGES/AMENDMENTS

If the investigator desires to modify any procedure and/or the design of the study, he or she must contact and obtain consent from JJSV regarding the proposed changes prior to implementation. Any modifications (including additional data collection) require approval of the governing IRB/IEC prior to implementation.

13. ETHICS REVIEW AND SUBJECT WELFARE

13.1 INDEPENDENT ETHICS COMMITTEE (IEC) OR INSTITUTIONAL REVIEW BOARD (IRB)

It is the responsibility of the investigator to obtain prospective approval of the study protocol, protocol amendments or changes, informed consent forms and other relevant documents (e.g., advertisements) from the IRB/IEC. All correspondence with the IRB/IEC should be retained in the Investigator Notebook. Copies of IRB/IEC submissions and approvals should be forwarded to JJSV.

The investigator is responsible for notifying the IRB/IEC of reportable adverse events as well as any other circumstance in which additional procedures outside the protocol were conducted to eliminate apparent hazards to subjects.

13.2 INFORMED CONSENT

The current version of the IRB/IEC-approved study informed consent must be signed by each study subject prior to any study-specific examinations being performed. The IRB/IEC-approved informed consent is to be signed and dated by the subject as well as by the person who conducted the informed consent discussion. The signed informed consent will be maintained by the investigator as a permanent part of the subject's medical records. A copy of the signed and dated form is to be provided to the subject. The investigator will provide JJSV written acknowledgement on the case report form that a signed agreement of informed consent has been obtained and is in the investigator's possession for each subject. As required by 21CFR812 Part G, the site shall document in the source documents that informed consent was obtained prior to participation in the study for each subject enrolled.

NOTE: The informed consent process also includes obtaining the subject's signature on an Authorization for Use/Disclosure of Health Information for Research Form or equivalent documentation necessary to comply with applicable privacy laws pertaining to medical measurement in the governing countries.

NOTE: The sponsor will secure appropriate insurance for study subjects prior to study start.

14. DOCUMENTATION

14.1 SOURCE DOCUMENTS

Source documents must be kept for all study subjects. Source documents may include a subject's medical records, hospital charts, clinic charts, the investigator's subject study files, as well as results of any diagnostic tests or procedures such as topographies or laboratory tests with photographs or instrument printouts.

Each site is expected to adhere to the clinic's own standard documentation requirements for medical charts/clinic notes. However, for the purposes of this clinical study, the medical charts/clinic notes must also include, at a minimum, the following data that will be considered source data and will be reviewed by JJSV:

- Subject's name and study identification number
- Subject's contact information
- Study protocol number and the Sponsor name (JJSV)
- A statement that informed consent was obtained prior to participation in the study (including the date)
- Dates of all subject visits throughout the duration of the study
- Concurrent medications
- Study measurements

- Description of any adverse events and/or product complaints/device deficiencies and documentation of appropriate reporting
- The date the subject exited the study, and a notation as to whether the subject completed the study or reason for early exit.

14.2 SUBJECT CONFIDENTIALITY

Subjects will be assigned a site/subject number to maintain subject confidentiality. Subject names may possibly be disclosed to the JJSV or regulatory agencies during inspection of medical records related to the study, but reasonable precautions will be taken to maintain confidentiality of personal information to the extent permitted by applicable laws and regulations.

14.3 CASE REPORT FORM COMPLETION

This study will use a paper or electronic data capture system. The investigator is responsible for ensuring that data are properly recorded on each subject's case report forms and related documents. Prior to database lock, the investigator will verify completeness and accuracy of data submitted to JJSV.

14.4 STUDY SUMMARY

A final investigator's summary will be provided to JJSV and the reviewing IRB/IEC within 3 months after termination or the completion of the study or the investigator's part of the investigation.

15. MONITORING

JJSV will perform three types of monitoring to ensure compliance with regulations: data monitoring, administrative monitoring, and safety monitoring.

15.1 DATA MONITORING

In order to ensure a well-controlled clinical trial, JJSV will follow specific data monitoring procedures, routinely generate reports and periodically review safety and effectiveness data. To avoid bias, any analyses generated prior to site closures will not be disseminated to any of the investigative sites.

To minimize data omissions and inconsistencies on clinical reports and to ensure that data are accurately transcribed to computer data files, JJSV will follow internal data processing procedures that include automated and manual quality control checks to identify any data discrepancies. Any such items will be resolved and documented as needed on the case report forms at the investigative site and in the data management system at JJSV.

Prevention of Missing Data

Methods used to safeguard against missing data that can have deleterious effects on the study integrity and reliability of its outcomes will include training study staff with centralized and on-site programs. In addition, subjects will be encouraged at the time of

informed consent to avoid missing study visits, as missing data may affect the study reliability and diminish the scientific value of their contribution to the study.

15.2 ADMINISTRATIVE MONITORING

Administrative monitoring procedures will ensure that study devices, subjects, and forms can be traced and will allow monitoring of investigator progress and compliance. Accountability and traceability of study devices will be monitored, as needed for compliance with study requirements.

Device Accountability

Complete Activator accountability will be maintained at the investigative site by maintaining records of investigational product received from and returned to JJSV. A site log will be used to track investigational equipment for date of receipt, use and disposition/return to JJSV. This site log and any other investigational product information will be maintained in the study binder and monitored by JJSV personnel. During periodic investigative site monitoring visits, JJSV personnel will review investigative product inventory records and logs to ensure Activator accountability compliance and complete investigational traceability.

Site Monitoring Plan

Prior to performing site initiation, the requirements of the study and reporting mechanisms will be explained to each investigator either personally at the investigative site or at a formal study investigator meeting. When necessary, a pre-study site qualification visit may be performed to assess the adequacy of the site to perform the study for sites that have not previously worked with JJSV or have undergone significant changes, or have not been visited in the past year. A study initiation visit will be conducted (either in-person or via a web-based meeting) for all sites prior to or at the time of the first study procedure. A study initiation visit may be conducted prior to the first treatment.

Throughout the duration of the study, site visits to monitor compliance to this protocol will be made at each investigative site. During interim site monitoring visits, JJSV will review informed consent documents and subject eligibility, and the data on study case report forms will be verified against subject charts and other source documents to ensure complete and accurate reporting. The subject files will also be reviewed to assure that all adverse events and any issues encountered with JJSV products have been reported in a timely fashion.

JJSV will also review source documents to verify that all required items have been documented in the subject medical charts. Refer to Section 14.1, Source Documents, for a list of items that are required for source documentation.

Training on study-specific procedures may also be conducted during monitoring visits.

Upon study completion, a final close-out site visit to each site will be made to monitor the last of the subject data records and finalize any outstanding study issues.

A separate Study Monitoring Plan will be established prior to study start that will define the type and frequency of monitoring visits and frequency of record monitoring.

15.3 SAFETY MONITORING

The Medical Monitor will review results throughout the clinical trial as necessary to ensure the continued safety of the device and to ensure that no subjects are exposed to unreasonable risk. The medical monitor will be available to answer all questions from investigators. The Medical Monitor will review and assess any reports of serious and/or device-related adverse events as well as device deficiencies that could have led to a serious adverse event, and discuss these with the reporting investigator(s) as necessary. The Medical Monitor, as well as any other qualified personnel designated by JJSV, shall also review any interim progress reports, as applicable.

16. PUBLICATIONS

Refer to the Clinical Trial Agreement for information regarding JJSV publication policies.

17. RISK ANALYSIS

Potential Risks and Risk Management

For the VERITAS™ Vision System, residual risks with rating of medium to the subjects and operators can be grouped into possible induced harms;

1) Corneal burn
2) Eye contamination – such as endophthalmitis
3) Subject or user injury– such as pinch, cut, bruise
4) Posterior capsular tear – can lead to vitreous traction, vitreous loss, and/or posterior dislocation of the cataractous lens
5) Anterior capsular tear – can lead to IOL unable to be placed in capsular bag
6) Endothelial cell loss
7) Electrical shock
8) Burn (second degree)
9) Environment: Fire
10) Laceration
11) Irregular pupil or Iris Damage
12) Vitreous Wick Syndrome

General risks of cataract surgery and IOL implantation

There are risks and complications associated with cataract surgery and IOL implantation in general. These can include worsening of vision, hemorrhage, loss of corneal clarity, inflammation, infections, retinal detachment, pupil changes, glaucoma, etc. Complications can result in poor vision, loss of vision or loss of the eye.

Risk Management

Subjects will be closely monitored throughout the trial duration. The occurrence of adverse events and complaints will be assessed at each study visit and reported to JJSV according to Section 11.0, Adverse Events and Product Complaints. Additionally, JJSV will monitor incoming data following the procedures outlined in Section 15.0, Monitoring. The Medical Monitor will ensure subjects are not exposed to additional risks by monitoring serious adverse events, device-related adverse events, and device-deficiencies that could have led to serious adverse events (Section 15.3, Safety Monitoring).

Potential Benefits

The subjects may experience the following benefits:

- Rapid visual rehabilitation and alleviation of symptoms due to cataract.
- Early resumption of daily activities
- Minimal ocular inflammation
- Minimal postoperative astigmatism
- Reduced potential for ocular complications

Subjects who are participating in this trial may benefit from improved visual outcomes due to the phacoemulsification procedure.

Conclusion

The hazards/risks associated with the VERITAS™ Vision System are acceptable and within those of JJSV's other phacoemulsification systems. The potential clinical benefits of the VERITAS™ Vision system outweigh the residual risks when the device is used as intended.

18. RECORDS RETENTION

All study-related correspondence, subject records, consent forms, Authorization for Use/Disclosure of Health Information Forms or similar medical treatment privacy law documentation, records of use of all study products, and original case report forms should be maintained by the investigator.

The investigator must maintain and have access to the following essential documents until notified by the Sponsor. Note: This may be for a minimum of 15 years after completion of the study unless country-specific requirements are longer. JJSV requires notification if the investigator wishes to relinquish ownership of the data so that mutually agreed-upon arrangements can be made for transfer of ownership to a suitably qualified, responsible person.

- All case report forms
- All adverse event information (detailed adverse event forms, follow-up letters, etc.)
- Investigational supply records/inventory

- IRB/IEC approval documentation
- Study correspondence
- Study agreements
- Site visit documentation
- Protocol(s) and the reason for any deviations from the protocol
- Subject log(s)
- Clinical Investigator's Brochure
- Completed subject informed consent forms and medical privacy forms (e.g., Authorization for Use/Disclosure of Health information or equivalent documentation necessary to comply with applicable privacy laws pertaining to medical treatment in the governing countries)
- Subject medical chart/clinic notes (Not applicable for transfer of ownership to JJSV)

19. TERMINATION OF THE INVESTIGATION

The clinical investigation will be suspended in the event of high levels of complications and/or adverse events that are unexpected in nature and/or severity and evaluated as to causality relative to the study device. The clinical investigation may be suspended if the Medical Monitor or IRB/IEC, upon review and evaluation of the clinical data, finds unacceptable clinical performance or the level of single or total complications and/or adverse events unacceptable for continuation of the investigation.

If causality is shown not to be related to the study device, the study may be resumed in accordance with the IRB/IEC and regulations of the FDA and governing countries. The study will be terminated if causality is shown to be related to the study device.

Additionally, the investigator, or JJSV, may stop a subject's participation at any time. JJSV may also stop the study at any time for reasons it determines appropriate. However, no suspension of the study would be made to disadvantage the study subjects. Following suspension of the study for any reason, all study subjects who have already received treatment would continue to be followed through completion of the study visit schedule.

20. STATISTICAL METHODS

20.1 ANALYSIS POPULATION

All subjects treated who have available data will be considered the safety population and used for all analyses.

20.2 STUDY ENDPOINTS

Primary Endpoints:

- Overall clinical performance will be evaluated based on surgeon's ratings and system log files, operative report and other medical records for the following items:

- Rating of anterior chamber stability
- Rating of followability
- Rating of holdability
- Rating of Phaco (cutting) efficiency
- Satisfaction with usability of VERITAS™ Vision System
- Overall satisfaction with VERITAS™ Vision System

Each of the questions will have a surgeon's rating score. The frequency and proportion of surgeon's ratings for each of the questions on a 1-5 rating scale will be reported. Clinical performance will be considered favorable for rating scores of 4 and above. The proportion and the associated 95% confidence interval of the rating scores of 4 and above for each question will be computed.

OTHER ENDPOINTS

- Effective Phaco Time (EPT)
- Ultrasonic Time (UST)
- Average Phaco Power (AVG)
- Volume of balanced salt solution (BSS) used
- Satisfaction with VERITAS™ Footpedal
- Satisfaction with VERITAS™ Swivel Handpiece
- Rating of corneal clarity at 1-day post-op
- Satisfaction with 1-day post-op clinical results of surgery with VERITAS™ Vision System
- Rate of adverse events and complications.

Summary statistics will be reported for the above endpoints. Continuous variables will be summarized by mean, standard deviation, minimum and maximum. Categorical variables will be reported by frequency and proportion.

20.3 SAMPLE SIZE CALCULATIONS

Minimum 55 eyes and up to 150 eyes will be treated to gain further surgeon experience with the new system.

A two-sided 95% confidence interval for an expected proportion of 0.95 using the large sample normal approximation will extend 0.058 (i.e., the precision of 5.8%) with a

sample size of 55 eyes and will extend 0.035 (i.e., the precision of 3.5%) with a sample size of 150 eyes.

APPENDIX A. SUMMARY OF PROCEDURES REQUIRED

Procedures	Visit 1: Preoperative Visit	Visit 2: Operative Visit	Visit 3: 1-Day Postoperative Visit
Informed consent	X		
Medical and Ocular History, inclusion/exclusion criteria	X		
BCDVA (Monocular)			X
UCDVA	X		X
Intraocular Pressure (IOP)	X		X
Slit-lamp Exam [a]	X	X	X
Anterior Chamber Depth (ACD)	X		X
Corneal Densitometry	X		X
Phacoemulsification Surgery		X	
Concomitant Medications (Ocular/Non Ocular)	X	X	X
Complications		X	X
Adverse events (Ocular/Non Ocular)	X	X	X
Device deficiencies/complaints		X	X
Ocular/visual Symptoms (Non-directed)	X		X
Surgeon Questionnaire		X[b]	X[c]

[a] Includes determination of ocular and lens findings/complications.

[b] The first 15 questions within the questionnaire, ratings at Operative Visit.

[c] The last 2 questions within the questionnaire, ratings at 1-Day Post-Op Visit.

APPENDIX B. EQUIPMENT LIST

The following equipment will be supplied to an investigative site for the duration of the study provided that the site does not already have such equipment available for use. This equipment loan will be documented in the Equipment Use Agreement or Clinical Trial Agreement, which indicates that the equipment is to be returned to JJSV at the completion of the study.

- VERITAS™ Vision System, which may include:
  - VERITAS™ Console with Power Cord
  - VERITAS™ Footpedal with Cable
  - VERITAS™ Swivel Handpieces system
  - VERITAS™ Remote Control
  - Phaco Pack (one for each case)
    - Advanced Fluidics Pack
    - Advanced Infusion Pack
- Solo I/A handpieces (if needed)
- Cart (if needed)
  - Mounting Plate
  - Motorized IV Pole
- Diathermy forceps or pencil handpieces, plus cables (if needed)
- 6 - 20 gauge vitrectomy kits, including 20 gauge irrigation sleeves (if needed)
- Phaco Tips (if needed)
  - 20 gauge phaco tips - 0º, 30º straight, curved 30º, plus sleeves
  - 21 gauge phaco tips - 0º, 30º straight, curved 30º, plus sleeves
- Digital video recorder and accessories to attach it to microscope (if needed)

Additional ancillary supplies may be provided to the site depending on their needs and surgical setup.

APPENDIX C. SLIT-LAMP EXAM RATINGS

The Investigator or designee assesses the findings for the presence of any medical findings.

A) Ratings of Aqueous Cells and Flare

For consistency, the SUN (Standardization of Uveitis Nomenclature) Working Group Grading Scheme is to be used for grading of anterior chamber cells and flare as reported in: Standardization of uveitis nomenclature for reporting clinical data. Results of the first international workshop; The standardization of uveitis nomenclature (SUN) working group. Am J Ophthalmol 2005;140:509-516.

CELLS

Grade	Cells in Field (Field is a 1x1 mm slit beam)
0	<1
0.5+	1 - 5
1+	6 - 15
2+	16 - 25
3+	26 - 50
4+	>50

FLARE

Grade	Description
0	None
1+	Faint
2+	Moderate (iris and lens details clear)
3+	Marked (iris and lens details hazy)
4+	Intense (fibrin or plastic aqueous)

B) Ratings of Corneal Edema

Corneal edema should be classified according to the haziness of the epithelium, the number of microcysts observed, and the clouding of the stroma.

Amount	Grade	Description
None	0	Normal transparency: a. No epithelial or sub-epithelial haziness b. No microcysts c. No stromal cloudiness

Amount	Grade	Description
Trace	+1	a. Barely discernable localized epithelial or sub-epithelial haziness, and/or b. 1 to 20 microcysts, and/or c. Barely discernable localized stromal cloudiness
Mild	+2	a. Faint but definite localized or generalized epithelial, sub-epithelial or stromal haziness/cloudiness, and/or b. 21-50 microcysts
Moderate	+3	a. Significant localized or generalized epithelial, sub-epithelial or stromal haziness/cloudiness and/or b. 51-100 microcysts
Severe	+4	a. Definite widespread epithelial or stromal cloudiness, giving dull glass appearance to cornea or numerous coalescent bullae (please note the number and location of bullae), and/or b. >100 microcysts or bullae, and/or c. Numerous striae (please note the number and location of striae or folds)

C) Ratings of Corneal Clarity

Corneal clarity should be classified according to the haziness and its effect on refraction.

Corneal Clarity	
0	Clear Cornea
1	Mild haze
2	Moderate haze
3	Dense haze / prevents refraction, Anterior Chamber visible
4	Dense haze / Anterior Chamber not visible

D) Posterior Capsule Striae Grading Scale

The following five-point grading scale is to be used for rating striae in the posterior capsule:

Amount	Grade	Description
None	0	None
Trace	+1	One detectable, barely noticeable striae
Mild	+2	One or two prominent striae
Moderate	+3	Three or more prominent striae, but visibility of retina is not impacted
Severe	+4	Three or more prominent striae affecting visualization of retina

E). Posterior Capsule Opacification Grading Scale

Below is the five-point grading scale to be used for PCO determination:

Amount	Grade	Description
None	0	Normal posterior capsule with no area of opacity. Red reflex bright.
Trace	+1	Some loss of transparency involving the posterior capsule. Red reflex fairly bright
Mild	+2	Mild loss of transparency with cloudiness extending through most of the posterior capsule. There may be a few Elschnig's pearls in the posterior capsule. Red reflex mildly diminished.
Moderate	+3	Moderate loss of transparency with difficulty visualizing the retina. There may be multiple Elschnig's pearls in the posterior capsule. Red reflex markedly diminished.
Severe	+4	Posterior capsule very opaque with inability to view the retina. The posterior capsule may have confluent Elschnig's pearls and fibrous scarring. Red reflex barely visible.

APPENDIX D. NEXT GENERATION PHACO SYSTEM (VERITAS™ VISION SYSTEM) PERFORMANCE RATING QUESTIONNAIRES

VERITAS™ Vision System Performance Rating at Operative Visit

The following questions should be completed by the surgeon after completion of each of the study cases.

Unsatisfied	Somewhat Unsatisfied	Neither Satisfied nor Unsatisfied	Satisfied	Very satisfied	Not Applicable
1	2	3	4	5	N/A

Rate the following regarding your satisfaction with the VERITAS™ Vision System, using 1 - 5 scale above. Your acceptability will be considered favorable for scores of 4 and 5.

If you rate a score of 1 or 2 on a question, please provide the feedback on the corresponding comment space.

Subject Study ID: _____ Study Eye: OD / OS

Surgeon: _____ Date: _____

1. Rating of satisfaction with responsive fluidics to quickly achieve and maintain chamber stability: 1 2 3 4 5 N/A

Comments: _____

2. Rating of satisfaction with post-occlusion surge: 1 2 3 4 5 N/A

Comments: _____

3. Rating of overall satisfaction with achieving and maintaining excellent anterior chamber stability: 1 2 3 4 5 N/A

Comments: _____

4. Rating of satisfaction with followability: 1 2 3 4 5 N/A

Comments: _____

5. Rating of satisfaction with holdability: 1 2 3 4 5 N/A

Comments: _____

6. Rating of satisfaction with Phaco (cutting) efficiency: 1 2 3 4 5 N/A

Comments: _____

7. Rating of satisfaction with corneal clarity at same day post-op:

1 2 3 4 5 N/A

Comments: _____

8. Rating of satisfaction with enhanced ergonomics of **VERITAS™ Footpedal**:

1 2 3 4 5 N/A

Comments: _____

9. Rating of overall satisfaction with **VERITAS™ Footpedal**:

1 2 3 4 5 N/A

Comments: _____

10. Rating of satisfaction with weight and size of **VERITAS™ Swivel Handpiece**:

1 2 3 4 5 N/A

Comments: _____

11. Rating of satisfaction with surgeon control of **VERITAS™ Swivel Handpiece**:

1 2 3 4 5 N/A

Comments: _____

12. Rating of overall satisfaction with **VERITAS™ Swivel Handpiece**:

1 2 3 4 5 N/A

Comments: _____

13. Rating of satisfaction with usability of **VERITAS™ Vision System**:

1 2 3 4 5 N/A

Comments: _____

14. Overall rating of satisfaction with **VERITAS™ Vision System**:

1 2 3 4 5 N/A

Comments: _____

15. Please comment on any pertinent observations you have after using the VERITAS™ Vision System:

Comments: _____

_____

_____

Surgeon Signature and Date: _____

VERITAS™ Vision System Performance Rating

at 1-Day Postoperative Visit

The following questions should be completed by the surgeon after completion of each of the study cases.

Unsatisfied	Somewhat Unsatisfied	Neither Satisfied nor Unsatisfied	Satisfied	Very satisfied	Not Applicable
1	2	3	4	5	N/A

Rate the following regarding your satisfaction with the VERITAS™ Vision System, using 1 - 5 scale above. Your acceptability will be considered favorable for scores of 4 and 5.

If you rate a score of 1 or 2 on a question, please provide the feedback on the corresponding comment space and share why it's rated as such.

Subject Study ID: _____ **Study Eye: OD / OS**

Surgeon: _____ **Date: _____**

1. Rating of satisfaction with corneal clarity at 1-Day Post-Op:

1 2 3 4 5 N/A

Comments: _____

2. Rating of satisfaction with 1-Day Post-Op clinical results of surgery with VERITAS™ Vision System (based on the results of UCDVA, corneal clarity, adverse event rate, and other relevant clinical assessment):

1 2 3 4 5 N/A

Comments: _____

_____

_____

Surgeon Signature and Date: _____

APPENDIX E. ADVERSE EVENT AND COMPLAINT REPORTING INSTRUCTIONS

All adverse events and complaints related to using JJSV products must be reported to JJSV.

All adverse events and complaints:

For events that are not considered serious or related to the study device:

1. Record the event and/or complaint on the case report form that corresponds to the visit during which awareness of the event occurred. Additionally, a complaint may be reported via a telephone call to JJSV.
2. Complete the case report form (CRF) in a timely manner.

Serious Adverse Events or device deficiencies that may have led to a serious event

In the event of a serious event (i.e., life- or sight-threatening incident) whether or not related to the device, or a device deficiency that may have led to a serious event, the investigator shall:

1. Notify JJSV immediately (no more than 24 hours after learning of the event) as follows:
   a. Contact the following JJSV personnel by phone and/or email:
      [redacted]
      Office: [redacted]
      Cell: [redacted]
      [redacted]
   b. Complete an Adverse Event Form and submit to JJSV

Non-serious, device-related Events:

For events that are not considered serious but are believed related to the study device (ADEs):

1. Complete an Adverse Event Form
2. Ensure the data are submitted to JJSV within a timely manner.

APPENDIX F. LIST OF POTENTIAL PRINCIPAL INVESTIGATORS AND SUB-INVESTIGATORS

List of Potential Principal Investigators (PIs) and Sub-Investigators (Sub-Is)		
No.	**Name**	**Location**
1	[redacted]	San Salvador, El Salvador
2	[redacted]	San Salvador, El Salvador
3	[redacted]	IN, USA
4	[redacted]	WI, USA
5	[redacted]	CA, USA
6	[redacted]	OH, USA
7	[redacted]	NY, USA
8	[redacted]	SD, USA
9	[redacted]	CA, USA
10	[redacted]	FL, USA
11	[redacted]	CA, USA
12	[redacted]	CA, USA