Short Title

ClarVista CP-00001

Long Title

A PROSPECTIVE, MULTI-CENTER, FEASIBILITY TRIAL OF THE CLARVISTA HARMONI™ MODULAR INTRAOCULAR LENS SYSTEM FOR THE TREATMENT OF APHAKIA FOLLOWING CATARACT SURGERY

1 TITLE PAGE

Protocol Number:	ClarVista CP-00001
Medical Specialty:	Surgical
Project Name /Number:	NA
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Test Article(s) / Product(s):	ClarVista HARMONI® Modular Toric Intraocular Lens System

TITLE PAGE

A PROSPECTIVE, MULTI-CENTER, FEASIBILITY TRIAL OF THE CLARVISTA HARMONI™ MODULAR INTRAOCULAR LENS SYSTEM FOR THE TREATMENT OF APHAKIA FOLLOWING CATARACT SURGERY

Protocol Number **#CP-00001 REV.05**

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[redacted]

Amendment 4 (Rev.05) **14 March 2016**

This clinical investigation is being conducted in accordance with 21 CFR Parts 11, 50, 54, 56, and 812, ISO 14155 (2011) Clinical Investigation of Medical Devices for Human Subjects, ISO 11979-7:2014 Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations, ANSI Z80.7-2013 Ophthalmic Optics – Intraocular Lenses , ICH GCPs, and applicable local regulations.

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PROTOCOL APPROVAL

A Prospective, Multi-Center, Feasibility Trial Of The ClarVista HARMONI™ Modular Intraocular Lens System For The Treatment Of Aphakia Following Cataract Surgery

The following individuals approve Protocol #CP-00001 Rev.05 dated 14 March 2016. Any changes to this version of the protocol must have an amendment or administrative letter.

ClarVista Approvals:

STUDY ACKNOWLEDGEMENT

I understand this protocol contains information that is confidential and proprietary to ClarVista Medical (ClarVista).

I have read this protocol and agree that it contains all the details necessary to conduct the study as described. I will follow this protocol in the conduct of the study and will make a reasonable effort to complete the study in the time noted.

I will provide the contents of this protocol to study staff under my direct supervision in order to conduct the study. I will discuss this information with the study staff to ensure they are fully informed about the study and the test article. I will provide the contents of the protocol to the responsible Ethics Committee. These disclosures may be made; providing the contents are not used in any other clinical study and they are not disclosed to any other person or entity without prior written consent from ClarVista. This condition does not apply to disclosure required by government regulations or laws; however, I agree to give prompt notice to ClarVista of any such disclosure.

I understand the study may be terminated or enrollment suspended at any time by ClarVista, with or without cause, or by me if it becomes necessary to protect the interests of the study subjects.

Any additional information added to this protocol is also confidential and proprietary to ClarVista and must be treated in the same manner as the contents of this protocol.

_____
Printed Name of Principal Investigator

_____ _____
Investigator Signature Date

Protocol # CP-00001 Rev.05
Amendment 4
Date: 14 March 2016

Table of Contents

TABLE OF FIGURES

LIST OF ABBREVIATIONS

Abbreviation/Acronym	Term
AE	Adverse Event
ACD	Anterior Chamber Depth
ADE	Adverse Device Effect
AL	Axial Length
ANSI	American National Standards Institute
BCDVA	Best-Corrected Distance Visual Acuity
BCNVA	Best-Corrected Near Visual Acuity
CFR	Code of Federal Regulations
D	Diopter
DD	Device Deficiencies
DFE	Dilated Fundus Examination
EC	Ethics Committee
[redacted]	
eCRF	Electronic Case Report Form
EPR	Error Predicted Refraction
ETDRS	Early Treatment Diabetic Retinopathy Study (Chart)
EtO	Ethylene oxide
FDA	United States Food and Drug Administration
GCPs	Good Clinical Practices
FE	Fellow Eye
HIPAA	Health Insurance Portability and Accountability Act
HMIOL	HARMONI™ Modular Intraocular Lens System
IB	Investigator Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
ID	Identification
IDE	Investigational Device Exemption
IOA	Intraoperative Aberrometry
IOL	Intraocular Lens
IOP	Intraocular Pressure
IRB	Institutional Review Board
ISO	International Organization for Standardization
K	Keratometry
LASIK	Laser In-Situ Keratomileusis
mBCDVA	Mesopic Best Corrected Visual Acuity
MR	Manifest Refraction
MRSE	Manifest Refraction Spherical Equivalent
MST	MicroSurgical Technology
Nd:YAG	Neodymium:Yttrium-aluminum-garnet
ND	Not Done
OD	Right Eye
OS	Left Eye
OVD	Ophthalmic Viscoelastic Device
PCO	Posterior Capsule Opacification
PH	Pinhole

PMA	Premarket Approval
PP	Per Protocol
PRK	Photorefractive Keratectomy
RRE	Residual Refractive Error
SAE	Serious Adverse Event
SIA	Surgically Induced Astigmatism
SLE	Slit Lamp Examination
SOC	Standard of Care
SPK	Superficial Punctate Keratitis
SSI	Secondary Surgical Intervention
TRRE	Target Residual Refractive Error
UCDVA	Uncorrected Distance Visual Acuity
UCNVA	Uncorrected Near Visual Acuity
US	United States
VA	Visual Acuity

NOTE: The first occurrence of some abbreviations are not spelled out in the document (e.g. units of measure).

PROTOCOL SYNOPSIS

Protocol Number #CP-00001 Rev.05	
Title	A Prospective, Multi-Center, Feasibility Trial Of The ClarVista HARMONI™ Modular Intraocular Lens System For The Treatment Of Aphakia Following Cataract Surgery
Regulatory Status	Feasibility (Pre-IDE)
Investigational Device	ClarVista HARMONI™ Modular Intraocular Lens System, non-toric aspheric optic
Objectives	• To demonstrate the feasibility of HARMONI™ IOL (HMIOL) implantation and assembly in subjects undergoing cataract surgery. • To demonstrate the feasibility of the HMIOL optic component exchange procedure (performed 3 months following primary cataract extraction)
Number of Clinical Sites and Study Subjects	Up to 200 subjects will be treated in this study at up to 7 investigational sites. Enrollment will be monitored as outlined in Sample Size section and adjusted accordingly.
Study Duration	All subjects will have up to 18 months study participation (Cohort dependent – see Study Design) from time of consent to study exit. Total study duration will be approximately 24 months.
Study Design	Prospective, multi-center clinical study. All subjects will be seen for a Preoperative Visit to capture baseline measurements then undergo cataract surgery with primary eye (first implant) receiving a test lens (HMIOL). The investigator will determine if the test lens is to be implanted in OD or OS based on target refraction and the best interests of the subject. Safety and Effectiveness testing of the HMIOL design allows the Investigator and Subject to decide if an optic exchange in the primary study eye is in the best interests of the subject based on refractive outcome and target. This determination will be made at the 3 month visit. At the 3 Month Visit (post-primary cataract extraction), subjects with satisfactory (as determined by investigator and subject) outcomes in the study eye, or those opting not to pursue an optic exchange, will be entered into

	Cohort 1. Subjects who opt for an optic exchange procedure will be entered into Cohort 2. All fellow eyes will receive a commercially approved IOL and standard of care (SOC) follow-up for 12 Months. For purposes of accountability and analysis, there will be the following Cohorts: • All HMIOL Eyes Cohort (All eyes receiving study device) • HMIOL Cohort 1 (HMIOL eyes without optic exchange) • HMIOL Cohort 2 (HMIOL eyes with optic exchange) • Fellow Eyes Cohort **Post-Operative Visits** All HMIOL Eyes Cohort • 1 Day, 1 Week, 1 Month, 3 Month following primary cataract extraction HMIOL Cohort 1 (HMIOL subjects without optic exchange procedure) • 6 Month, and 12 Month Visits following primary cataract extraction HMIOL Cohort 2 (HMIOL subjects undergoing optic exchange) • Optic exchange decision and assignment to Cohort 2 at 3 Month Visit as deemed necessary by Investigator and Subject • 1 Day, 1 Week, 1 Month, 3 Month, 6 Month, and 12 Month Visits following optic exchange [redacted]
Study Endpoints	The safety and effectiveness of HMIOL for the treatment of aphakia in subjects following cataract extraction will be characterized along with the safety and effectiveness of the HMIOL optic exchange procedure in the subgroup of study subjects with optic exchange. **Safety Endpoints:** All HMIOL Eyes Cohort: • [redacted]

	• [redacted] • [redacted] • AE rates as compared to ISO 11979-7:2014 Annex B Safety and Performance Endpoint (SPE) tables • [redacted] • Secondary Surgical Intervention (SSI) HMIOL Cohort 1 • [redacted] • AE rates as compared to ISO 11979-7:2014 Annex B SPE tables • [redacted] • SSI HMIOL Cohort 2 • [redacted] • AE rates as compared to ISO 11979-7:2014 Annex B SPE tables • [redacted] • SSI (planned Optic Exchange procedures excluded) **Effectiveness Endpoints:** All HMIOL Eyes Cohort: • Percent of eyes with post-operative BCDVA 20/40 or better by study Visit • Percent of eyes that achieve MRSE of ±0.50 D of target by study visit • Percent of eyes that achieve MRSE of ±1.00 D of target by study visit • BCDVA by study visit • UCDVA by study visit • mBCDVA (with and without glare) by study visit HMIOL Cohort 1 • Percent of eyes with post-operative BCDVA 20/40 or better by study visit • Percent of eyes that achieve MRSE of ±0.50 D of target by study visit

	• Percent of eyes that achieve MRSE of ±1.00 D of target by study visit
	• BCDVA by study visit
	• UCDVA by study visit
	
	HMIOL Cohort 2
	• Percent of eyes with post-operative BCDVA 20/40 or better by study visit
	• Percent of eyes that achieve UCDVA by post-optic exchange study visit
	  ○ 20/20 or better
	  ○ 20/25 or better
	  ○ 20/32 or better
	  ○ 20/40 or better
	  ○ Worse than 20/40
	• Percent of eyes that achieve MRSE of ±0.50 D of optic exchange target by post-optic exchange study visit
	• Percent of eyes that achieve MRSE of ±1.00 D of optic exchange target by post-optic exchange study visit
	• BCDVA by study visit
	• UCDVA by study visit
	
	Planned Analyses:
	
	[redacted]
	
	Final Safety and Effectiveness outcomes will be evaluated when all study subjects complete final visit or exit the study.

Main Clinical Assessments	1) [redacted] 2) Uncorrected Distance Visual Acuity (UCDVA)

	3) Uncorrected Near Visual Acuity (UCNVA) 4) Best Corrected Distance Visual Acuity (BCDVA) 5) Best Corrected Near Visual Acuity (BCNVA) 6) Mesopic Best Corrected Distance Visual Acuity (mBCDVA) 7) Slit Lamp Exam (SLE) 8) [redacted] 9) Intraocular Pressure (IOP) 10) Dilated fundus exam (DFE) Masking Visual Acuity and Refraction testing will be conducted by study staff masked as to the subject's post-operative target SE up to the completion of the 3 Month Visit (post-primary cataract extraction). All other testing will be conducted by unmasked staff due to the expected unmasking from timing and frequency of the evaluation or visualization of the test article. [redacted]
Sample Size	The sample size of this feasibility study is first calculated based on ISO 11979-7:2014 (E) to evaluate the proportion of HMIOL-implanted eyes with BCDVA of 0.3 logMAR of better for all HMIOL Cohort (post optic exchange for HMIOL Cohort 2). The statistical hypotheses for the effectiveness are H0: $p \geq 0.925$ and Ha: $p < 0.925$, where p is the proportion of HMIOL-implanted eye with BCDVA of 0.3 logMAR. Based on the binomial distribution with a one-side significance level of 0.05 and a true p of 0.85, a sample size of 100 eyes will provide a statistical power of about 75%; while a sample size of 200 eyes will provide a statistical power of about 95%. Therefore, a sample size of 100 to 200 eyes implanted with HMIOL will be required for the study. For any adverse events that are not observed during the study, the one-sided upper 95% confidence limit of the adverse event rate is 0.0362 if the sample size is 100 eyes. The one-sided upper 95% confidence limit of the adverse event rate is 0.0183 if the sample size is 200 eyes. Therefore, a sample size of 100 to 200 deems to be sufficient for evaluating the safety and effectiveness of HMIOL for this feasibility study. [redacted]

	[redacted] The goal will be to enroll up to 200 subjects. However, after the first 25 subjects have reached the 3 month time point (and every 25 subjects thereafter), subject accountability and the rate of optic exchanges will be evaluated, and the enrollment goal will be reevaluated with respect to achieving the necessary sample size. It should be noted that this is a feasibility study. All the analyses are to evaluate the effectiveness and safety of the HMIOL for the future confirmatory study. No adjustment is performed for the multiplicity.

[redacted]

1.0 INTRODUCTION

Cataract surgery is a minimally invasive procedure designed to restore vision with short recovery time. Advances in instrumentation and techniques over the past few decades have facilitated the enhancement in safety[1] while allowing for reproducible outcomes. While the serious adverse event rate remains low, selecting the right intraocular lens (IOL) implant for spectacle independence remains an on-going challenge. This is referred to as residual refractive error (RRE) and typically involves ~0.6 diopters (D)[2] of uncorrected focusing power. Furthermore, it is reported that current biometry measurements for selecting the correct IOL and subsequent surgical methods are associated with:

1. Up to 16% of patients undergoing additional surgical correction to achieve 20/20 unassisted vision[2].
2. Up to 55% of patients falling outside of their targeted postoperative refraction by at least 0.5D[3,4,5].
3. Between 14 and 24% of surgeries result in greater than 1 D of residual refractive error, when using manufacturer suggested constants[3].

Patients are frequently satisfied with the results of their cataract surgery and enjoy relatively quick recovery with restoration of vision. However, as expectations have evolved over time, patients are demanding the same degree of spectacle independence that other refractive surgeries such as LASIK provide. Currently available options to help achieve spectacle independence when RRE is present include: contact lenses, corneal modification (surgery or other), IOL exchange/manipulation, or sulcus placement of a "piggyback" IOL. These alternatives have significant limitations and risks.

Complications due to contact lenses are rare; however, contact lens intolerance and contact lens-related infections could be serious and sight threatening. For some patients, contact lens wear is contraindicated and they must resort to the use of spectacles. Elderly patients in particular have difficulty handling contact lenses.

If the patient is willing to accept the additional cost and risks of a secondary procedure, the physician has more options; however, each of them poses a significant risk to the patient as outlined below.

Corneal modifications have been performed on tens of millions of people across the world with some form of refractive surgery (e.g. LASIK). For example, in the U.S. (where the most extensive data exists) 11.5M Americans have had corneal refractive surgery and over the next two decades many will need cataract surgery. LASIK increases the likelihood for residual refractive error post cataract surgery due to inaccurate IOL power calculations with biometry. There is hesitation among many ophthalmologists to repeat LASIK for RRE after cataract surgery because the FDA has not specifically evaluated the safety and effectiveness of repeated LASIK in this setting. All the risks associated with the original LASIK procedure apply to retreatment, along with the increased potential for epithelial ingrowth, corneal ectasia and less robust nomograms for IOL selection for post cataract patients.

Furthermore, even for eyes that have not undergone prior corneal refractive surgery, the FDA has not specifically evaluated the safety and effectiveness of corneal refractive procedures (e.g., astigmatic keratotomy, LASIK, PRK, etc.) to address RRE following lens replacement surgery, so the use of approved lasers for this purpose in the U.S. is considered off-label and the risks are not well characterized. For example, it is unclear how optical aberrations that might be present with an IOL in place are increased by aberrations induced by corneal refractive procedures, how likely corneal refractive procedures are to induce irregular astigmatism and worsen dry eye that is induced by cataract surgery, and whether corneal refractive procedures could create potential complications related to cataract surgery wound healing or IOL stability.

Furthermore, cornea based interventions do not address the root cause of RRE after cataract extraction (imprecise IOL power selection) and expose the patient to a new and independent set of possible adverse events. Thus, it would be desirable to be able to correct or modify the optical result without the need to irreversibly and unpredictably alter corneal tissue following cataract extraction.

Sulcus placement of a "piggyback" IOL is a procedure that has not been evaluated for safety and effectiveness by the FDA so the use of approved IOLs for this purpose in the U.S. is off-label. Among the complications reported with this procedure are secondary pigment dispersion, iris/pupil irregularities, chronic iritis, hyphema, glaucoma, zonular disruption and/or posterior capsular rupture. Thus, it would be desirable to be able to correct or modify the optical result without the need to implant a "piggyback" IOL with its inherent serious risks.

IOL Exchange/Manipulation in general, is technically challenging for the surgeon and poses an iatrogenic risk to intraocular structures including the lens capsule, iris, and endothelium of the cornea. Manipulation of the capsular bag to remove an IOL is the major risk in this setting and can damage the capsular bag including posterior capsular rupture and capsular bag dislocation. The capsular bag cannot be repaired once damaged. This risk increases over time as the capsular bag adheres to the IOL and haptics. Even when IOL exchange is not required, manipulation of traditional IOL's to rotate or center the optic introduces the risk of capsular or zonular damage which can cause further lens instability and lens malposition. Thus, it would be desirable to be able to correct RRE without the need to remove the entire IOL particularly after capsular contraction or fibrosis.

The modular IOL concept will serve as a valuable addition to the armamentarium of cataract surgeons. The goal of this technology is to improve refractive (spherical and toric) outcomes and avoid the significant risks of secondary procedures currently being performed as standard practice to address RRE in an indirect manner. It is anticipated that this modular lens will provide clinical utility in two basic areas, the first being the focus of this study.

1. Post-operative correction of residual spherical refractive error – Based on existing performance of conventional cataract surgery, researchers have concluded that refractive outcomes in normal eyes should be within 0.5D for 45% and within 1D for 85% of cataract cases[3]. This theoretical performance goal still falls substantially short of the real-world outcomes seen with corneal refractive surgery and which cataract patients and surgeons increasingly demand. As a consequence, secondary procedures to optimize visual outcomes following cataract surgery can be as high as 16% in some practices, particularly for premium lens patients[2].

   Another common approach associated with residual spherical refractive error is referred to as monovision (which can be achieved with contact lenses, corneal refractive surgery, or IOL selection), a monofocal IOL which targets distance vision is used in the dominant eye and the opposite, the non-dominate eye is targeted for near vision. This approach allows patients to see at both distance and near and is a popular choice for patients wishing to achieve spectacle independence.

   While it is commonly used for this purpose, not all patients are able to adapt to monovision.[7,8,9,10] They may have difficulty with acuity-based tasks and with tasks demanding depth perception. Monovision patients may also experience problems with headaches and troublesome visual symptoms such as glare and halos around point sources of light, particularly under low-light conditions. Typically, within three months of the surgery a patient's acceptance or lack of acceptance of monovision correction will be known. At that point, dissatisfied patients are offered glasses to overcome the refractive disparity between eyes. Of course, this is contrary to the patient's desire to be independent of glasses. Furthermore, spectacle correction is not ideal due to the significant imbalance between the required lens power for each eye creating visual discomfort and intolerance (i.e. asthenopia). Refractive surgery on the cornea (e.g., LASIK or PRK) to reverse the over correction of the non-dominant eye is also an option, but not all monovision patients have a suitable cornea (e.g., too thin) and such surgery introduces additional risk.

   Modular IOL technology is intended to directly improve refractive outcomes without the inherent risk of a full lens exchange or resorting to the use of a corneal refractive laser. With the HARMONI™ design the spherical optic component is intended to allow exchange for a different power optic or adjusted to align with the visual axis without extensive manipulation of the delicate capsular bag, thereby avoiding the potential for intraocular (e.g., capsular and endothelial) trauma that is seen with traditional IOL exchanges.

2. Post-operative correction of displaced or off-axis toric lens – For every 1 degree a toric IOL axis is off from the true postoperative axis of astigmatism, there will be a 3.3% loss of toric correction. Study data supporting a recent approval of a toric IOL (P930014/S045) showed that 6.7% of eyes underwent a secondary surgical intervention (SSI) in the form of IOL repositioning to resolve RRE. The HARMONI™ modular technology can be used to improve outcomes in patients where the toric lens has been displaced to an unintended position during the post-operative period. The HARMONI™ optic allows for adjustment

to align with the astigmatic meridian or visual axis without manipulation of the base component thereby avoiding the potential for capsular trauma that is seen when approved toric IOLs are manipulated in the post-operative period.

2.0 OBJECTIVE

The primary objective of this study is to demonstrate the feasibility of the HARMONI™ Modular Intraocular Lens (HMIOL) System implantation & assembly in subjects undergoing cataract surgery. Additionally, the feasibility of the HMIOL optic component exchange procedure (performed 3 months following cataract extraction) will be examined.

3.0 STUDY DESIGN

3.1 DESCRIPTION OF THE STUDY

This is a prospective, multi-center, feasibility study being conducted at up to 7 investigative sites. All sites will have Institutional Review Board (IRB) or Ethics Committee (EC) review and approval prior to recruiting potential subjects. Up to 200 eligible subjects with bilateral cataracts will undergo cataract extraction in each eye during participation. Within approximately one to four weeks post-implantation of the HMIOL, the fellow eye (FE) will be implanted with a commercially available IOL.

At the 3 Month Visit (post-primary cataract extraction), subjects with satisfactory outcomes, or those opting not to pursue an optic exchange, will be entered into Cohort 1.

Subjects who opt for an HMIOL optic exchange in their primary eye will be entered into Cohort 2.

FIGURE 2 - COHORT DESIGNATION

All subjects enrolled in this study will be evaluated for 12 months following either primary cataract extraction or optic exchange, whichever is later (see Appendix A – Schedule of Assessments).

3.2 STUDY POPULATION

All subjects will be recruited from the site's clinic population or referrals from current or past patients. Opportunity for participation will be offered to all patients who show potential eligibility following standard of care evaluations. If the patient is interested in participation, the consenting process will be initiated (See section 4.1). After completing the informed consent process, subjects will be screened for participation in the study. No vulnerable populations (minors, incarcerated, cognitively impaired, etc) will be offered participation in this study.

3.2.1 INCLUSION CRITERIA

1. Must be able to understand and provide informed consent themselves or through a representative with a witness present on the IRB or EC approved Informed Consent Form (ICF)
2. Must be willing and able to return for scheduled treatment and follow-up examinations for up to 15 month study duration
3. Must be at least 22 years of age or older at the time of consent
4. Planned bilateral removal of visually significant bilateral cataracts (cortical, nuclear, subcapsular, or a combination) by manual phacoemulsification cataract extraction
5. Target dioptric lens power within the range of 18 - 26 D in the primary study eye
6. Must be willing to discontinue contact lens wear for the duration of the study and demonstrate refractive stability prior to biometry and surgery in the primary study eye
   NOTE: Due to potential variability of VA and MR outcomes following gas permeable (GP) contact lens wear, all subjects who have worn GP contact lenses must complete the consenting process, discontinue wear for 3 weeks and exhibit a stable Manifest Refraction (as evidenced by two MR evaluations at least 1 week apart resulting in ≤0.50D MRSE difference in the two refractions) and Keratometry readings (as evidenced by two K readings at least 1 week apart resulting in ≤0.50D difference between the two readings) prior to final IOL calculations. Similarly, any subjects who currently wear soft contact lenses must also complete the consenting process, discontinue wear for a minimum of 1 week and return for repeat eligibility testing exhibit stable MR and K readings. In addition, all qualifying subjects must discontinue contact lens wear in the study eye for the duration of study participation.
7. Must have BCDVA projected to be better than 20/32 after IOL implantation (as determined by the medical judgment of the Investigator or measured by potential acuity meter / retinal acuity meter (PAM / RAM) if necessary) in both eyes
8. Preoperative bilateral BCDVA 0.3 logMAR or worse (20/40 or worse) with or without Brightness Acuity Testing (BAT) or the presentation of symptoms including glare, halos, or visual obscuration negatively influencing the subject's quality of life
9. Both eyes must have corneal astigmatism ≤ 1.50 D
10. Dilated pupil size ≥ 6 mm in primary study eye
11. Women must be post-menopausal ≥1 year or surgically sterilized, or a pregnancy screen must be performed prior to the study and a reliable form of contraception, approved by the investigator, must be maintained during the study

3.2.2 EXCLUSION CRITERIA PRIOR TO SURGERY

1. Participation in any other drug or device clinical trial within 30 days prior to enrolling in this study and/or during study participation
2. History of any intraocular or corneal surgery in either eye (including refractive)

3. History of any clinically significant retinal pathology or ocular diagnosis (e.g. diabetic retinopathy, ischemic diseases, macular degeneration, retinal detachment, amblyopia, optic neuropathy, etc.) in either eye
4. History of any ocular conditions which could affect the stability of the IOL (e.g. pseudoexfoliation, zonular dialysis, evident zonular weakness or dehiscence, etc.) in either eye
5. Any anterior segment pathology likely to increase the risk of complications from phacoemulsification cataract extraction (e.g. chronic uveitis, iritis, iridocyclitis, aniridia, rubeosis iridis, clinically significant corneal, Fuch's, or anterior membrane dystrophies, etc.) in either eye
6. Traumatic or congenital cataract in the either eye
7. Any visually significant intraocular media opacity other than cataract in either eye (as determined by the investigator)
8. Uncontrolled glaucoma in either eye (per Investigator judgement)
9. Central endothelial cell count < 2000 cells/mm² in either eye at the Pre-Operative Visit as determined by the reading center (see Manual of Procedures).
10. Subjects with large refractive errors (hyperopia/myopia) of axial or pathologic origin that, in the opinion of the investigator, could confound outcomes
11. Subject who are pregnant, lactating, or planning to become pregnant during the course of the study
12. Uncontrolled systemic disease (e.g. diabetes mellitus, active cancer treatment, mental illness, etc)
13. Subject who, in the clinical judgment of the investigator, is not suitable for participation in the study for another clinical reason, as documented by the investigator
14. Severe dry eye that, in the opinion of the investigator, would impair the ability to obtain reliable study measurements (e.g. specular microscopy)
15. Taking systemic medications that, in the opinion of the investigator, may confound the outcome or increase the risk to the subject (e.g. Tamsulosin Hydrochloride – Flomax) or other medications including anticholinergics, alpha adrenergic blocking agents with similar side effects (e.g. small pupil/floppy iris syndrome)

3.2.3 EXCLUSION CRITERIA DURING SURGERY

1. Vitreous loss prior to use of the investigational device
2. Positive posterior pressure preventing safe implantation of the lens system
3. Anterior chamber hyphema preventing visualization of implantation
4. Any zonular or capsular rupture or capsular bag instability

5. Intraoperative miosis preventing visualization of fixation features
6. Need for concomitant procedures (e.g. glaucoma surgery, LRI, RK, LASIK, etc.)
7. Subject who, in the clinical judgment of the investigator, is not suitable for participation in the study for another clinical reason, as documented by the investigator

3.2.4 EXCLUSION CRITERIA – 3 MONTHS POST-PRIMARY CATARACT EXTRACTION (AFFECTING ELIGIBILITY FOR HMIOL OPTIC EXCHANGE)

1. Any clinical finding or intraocular complication during primary cataract extraction that (in the judgment of the Investigator) is likely to increase complications with optic exchange procedure or present undue risk to the subject (e.g. unexplained endothelial cell loss, post-primary cataract extraction macular edema, persistent ocular inflammation, etc.)
2. Presence of YAG Capsulotomy in the primary (HMIOL) eye

3.3 STUDY VISITS

The timing and frequency of each assessment to be performed at each visit, will be carried out according to "Appendix A – Schedule of Assessments."

Procedures to be followed in order to carry out each individual assessment, are under separate cover (See study specific Manual of Procedures).

In all instances, if the primary study eye (received HMIOL) and FE post-operative assessments cannot be seen on the same day and both remain "in-window," the subject must return for a separate visit in order to maintain "in-window" status for both eyes throughout study participation.

3.3.1 PRE-OPERATIVE VISIT – SCREENING/BASELINE (DAY -90 TO DAY -1)

After providing informed consent (see Section 4.1), prospective subjects will be screened to determine whether they meet enrollment criteria. Demographic information, relevant ocular history, and current ocular medication use will be collected. If all criteria are met, the subject will be considered enrolled, IOL calculation completed to determine appropriate HMIOL power, and the subject scheduled for surgery.

3.3.2 DAY 0 VISIT (PRIMARY CATARACT EXTRACTION SURGERY)

Record any changes in concomitant medications and medical history, prepare the subject for surgery in the study eye (see Surgical Procedure Guide), and re-review inclusion/exclusion criteria to ensure subject still qualifies to participate.

The Investigator will carry out the surgical procedure and HMIOL implantation as specified in the Surgical Procedure Manual and the following details will be captured in both Source Documents and eCRFs:

- Date of surgery
- Operative eye
- Test or Fellow Eye
- Incision location and size

- Capsulorhexis size
- Ophthalmic Viscoelastic Device (OVD) used
- All medication used pre-, intra-, and post-operatively (ophthalmic and systemic)
- Surgical times
- Model, serial number, and diopter of HMIOL implant components
- IOL injection device

Once the subject is confirmed stable post-surgery, provide IRB / EC approved post-operative instructions and discharge.

Record any AEs, adverse device effects (ADEs), unexpected adverse device effects (UADEs), or device deficiencies (DD) (see Sections 6.1.1, 6.1.2, 6.1.3, or 6.1.4 respectively) observed pre-, intra-, or post-operatively.

In the event the subject is not implanted with an HMIOL device due to an intra-operative complication, the subject will be discontinued (see Section 4.5).

3.3.3 POST-OPERATIVE VISITS (DAYS 1 – 60)

All subjects implanted with a study lens will be seen for 1 Day, 1 Week, and 1 Month assessments as outlined in Appendix A.

IN ADDITION, the fellow eye (FE) will be implanted with a commercially available IOL, during this time period. It is recommended (at the final discretion of the Investigator), to complete this procedure as close to the 1 Week Visit (post-primary cataract extraction) as possible. Since FE assessments will be completed on the same schedule as the primary eye assessments (see Appendix A – Table 2), this will allow the subject further convenience in attending as many post-operative bilateral assessment visits as possible.

The Investigator will carry out the FE surgical procedure and follow-up per Standard of Care (SOC) and the following details will be captured in both Source Documents and eCRFs:

- Date of surgery
- Operative eye
- Test or Fellow Eye
- Incision location and size
- Capsulorhexis size
- Ophthalmic Viscoelastic Device (OVD) used
- All medication used pre-, intra-, and post-operatively (ophthalmic and systemic)
- Surgical times
- Model, serial number, and diopter of IOL
- IOL Injection device

Once the subject is confirmed stable post-surgery, provide post-operative instructions and discharge.

NOTE: All concomitant medication, AE, and SAE collection must be continued throughout the course of the study. Any FE outcomes resulting in unacceptable RRE (as determined between Investigator and Subject), can be addressed with spectacles, a contact lens, or surgical correction. Any PO surgical adjustments to FE outcomes (corneal refractive surgery, lens exchange, etc) will be carried out as determined to be in the best interest of the subject. The course of treatment will follow the Investigators SOC and be collected as a concomitant procedure on the non-study eye.

3.3.4 3 MONTH VISIT (DAY 80-100)

Bilateral assessments will be completed as indicated in Appendix A – Tables 1 and 2. In the event the FE is out of window at this visit, the subject will return in-window to complete FE assessments.

At the 3 month visit, an overall assessment of a subject's visual function will be performed by the physician. If the physician's assessment results in an opportunity for improved visual function through optic exchange in the test eye, the subject will be offered that opportunity. The Investigator and the Subject will decide if an optic exchange is appropriate.

The decision will be documented and the prospective Cohort indicated.

- If the subject has an acceptable outcome or it is otherwise decided an optic exchange will not take place, the subject will be entered into Cohort 1 and be followed at the 6 and 12 Month Visits prior to study completion. If the subject desires an exchange, however it is decided they cannot have one based on exclusion criteria (Section 3.2.4), the subject will remain in Cohort 1 and can utilize spectacles to correct RRE for the remainder of study participation. The investigator and subject can decide on further treatment per the Investigator's standard of care, following study participation.
- If it is decided an HMIOL optic exchange is desired, the appropriate pre-operative measurements will be obtained, 3 Month Visit assessments completed per Appendix A – Table 1, and HMIOL calculations and optic ordered. Finally, the subject will be scheduled for the procedure and entered into Cohort 2 (finalized after successful completion of optic exchange). If for any reason the optic exchange procedure does not take place, the subject will default back to Cohort 1.

3.3.5 COHORT 1: 6 AND 12 MONTH VISITS

All subjects entered into Cohort 1 will be seen for 6 and 12 Month Visits (post-primary cataract extraction) for bilateral assessments and exited from the study (See Appendix A – Table 1).

NOTE: All concomitant medication, AE, ADE, DD, and SAE collection must be continued throughout the course of the study.

3.3.6 COHORT 2: OPTIC EXCHANGE VISIT (3 MONTH VISIT +1-21 DAYS)

Record any changes in concomitant medications and prepare the subject for optic exchange surgery in the study eye (see Surgical Procedure Guide).

The Investigator will carry out the optic power determination, surgical procedure, and HMIOL optic exchange as specified in the Surgical Guide and the following details will be captured in both Source Documents and eCRFs:

- Date of surgery
- Operative eye
- Incision location and size
- Ophthalmic Viscoelastic Device (OVD) used
- All medication used pre-, intra-, and post-operatively (ophthalmic and systemic)
- Surgical times
- Model, serial number, and diopter of HMIOL Optic
- HMIOL Optic injection device

Once the subject is confirmed stable post-surgery, provide IRB / EC approved post-operative instructions and discharge.

Following successful completion of HMIOL optic exchange, the subject is entered into Cohort 2. Record any AEs, ADEs, UADEs, or DDs (see Sections 6.1.1, 6.1.2, 6.1.3, or 6.1.4 respectively) observed pre-, intra-, or post-operatively.

3.3.7 COHORT 2: POST-OPERATIVE VISITS (DAYS 1 - 420 POST-OPTIC EXCHANGE VISIT)

All subjects in Cohort 2 will be seen for 1 Day, 1 Week, 1 Month, 3 Month, 6 Month and 12 Month (post-optic exchange) assessments. (see Appendix A – Table 3).

NOTE: All concomitant medication, AE, ADE, UADE, DD, and SAE collection must be continued throughout the course of the study.

3.3.8 UNSCHEDULED VISITS

If at any time during the study, outside of the above scheduled visits, the subject requests or the Investigator determines the subject should be assessed, an unscheduled visit may occur. Adverse events and concomitant medications will be recorded and assessments deemed necessary by the Investigator should be performed on either or both eyes. NOTE: Only data relevant to the primary study eye (if applicable) will be captured on the Unscheduled Visit eCRFs.

If a subject is seen for multiple visits during a given visit window, the data from a visit that is intended to meet the protocol requirements for the scheduled visit should be captured in the visit eCRF. Where such a determination cannot be made, the first visit within the scheduled visit window will be used for completion of the protocol required visit. If assessments are missing from that visit, however captured at subsequent visits within window, those assessments can be collected as part of the protocol visit. In such a circumstance, the visit date will remain consistent with the first visit established within the visit window, per the scenario above. Any additional and applicable data captured and associated with the Study Eye will be captured as an Unscheduled Visit.

3.3.9 MISSED VISITS

If a subject misses any scheduled visit and cannot be seen prior to the start of the next visit window, the visit will be considered "missed."

4.0 STUDY METHODS

Prior to recruitment of any subjects into the study, review and written approval of the protocol and informed consent must be obtained from the Institutional Review Board (IRB) or Ethics Committee (EC) by each participating clinical site.

4.1 INFORMED CONSENT

Informed consent must be obtained and documented in writing prior to the initiation of any study procedures. The subject (or the subject's legally authorized representative) must be allowed sufficient time to thoroughly read (or have explained), the informed consent form. The Investigator or his/her designee should answer any questions that the subject/representative might have. If the subject agrees to participate in the study, (i.e. provides informed consent) the subject/representative must sign two copies of the informed consent form. The witness and the Investigator must also sign both copies of the informed consent form. One copy of the informed consent form should be given to the subject/representative. If applicable, it will be provided in a certified translation of the local language. As part of the consenting process, the subjects will be informed of their right to treatment for any injuries related to the study. Any and all such treatment if necessary, will be paid for by the Sponsor to the extent it is not covered by a subject's healthcare coverage (subject to local ethics committee approval). Completion of the consenting process as well as the date of the subject's signature on the informed consent form should be noted in the subject's medical chart.

Subjects who complete the informed consent process will be screened for eligibility. Screened subjects will be recorded on site-specific screening logs and once they are determined as being eligible, they will be enrolled into the study and an HMIOL order placed with the Sponsor if necessary. All eligible subjects will receive a stipend to attend scheduled study visits as an allowance for food, time, and travel expenses.

Subjects will complete the Investigator's standard of care (SOC) consent process for the FE procedure.

Subjects scheduled for an optic exchange will complete an addition IRB / EC approved informed consent process for this procedure.

4.2 ASSIGNMENT OF SUBJECT IDENTIFICATION

A unique and sequential subject identification number (ID) will be assigned at screening and never duplicated for another subject. This ID will be used on all study-related documents. To maintain confidentiality, the subject's name will not be recorded on any study document other than the informed consent form.

4.3 SCREEN FAILURE

A record of screen failures and the reasons for the screen failures will be recorded in the subject source documents and captured in the eCRF for summary.

4.4 SUBJECT COMPLETION

The subject has completed the entire study when the HMIOL has been implanted and / or the Optic Exchange completed and the Sponsor receives completed electronic Case Report Form (eCRF) documentation for all visits and a Study Exit eCRF. Subjects who require further follow-up for an AE will be followed according to Section 6.3.4.

A Study Exit eCRF must be completed for all subjects who complete the clinical investigation.

4.5 SUBJECT DISCONTINUATION

A subject MUST be discontinued prior to the final study visit for any of the following reasons:

- Death
- Subject is enrolled and scheduled for surgery but is not implanted with an HMIOL at Day 0 (Operative Visit – Primary Cataract Extraction)
- Surgical complication(s) unrelated to the investigational device preventing the implantation of the HMIOL (i.e. capsulorhexis tear, zonular rupture, evident zonular weakness or dehiscence, posterior capsular rupture, vitreous loss, posterior capsular plaque, significant detached Descemet's membrane, significant anterior chamber bleeding, iris incarceration or damage, corneal endothelial touch, unsuccessful/incomplete phacoemulsification, haptic and/or optic damage/haptic amputation)
- Explantation of the HMIOL System

If the study lens is explanted, one postoperative visit should be completed to record best-corrected distance visual acuity (BCDVA) before the subject is discontinued.

Subjects who withdraw from the study will be asked to complete procedures outlined in the 12 Month Visit (if withdrawn prior to that visit). Subjects who are terminated due to an AE will be followed, if possible, at least until resolution or stabilization of the AE. Subject withdrawals will be documented clearly on the source document and applicable eCRF.

Prior to discontinuing a subject, every effort should be made to contact the subject, schedule a final study visit, and obtain as much follow-up data as possible. Adverse events will be followed as described in Section 6.3.4. Discontinued subjects should be followed outside of the study protocol according to the Investigator's normal postoperative standard of care.

A Study Exit eCRF must be completed for all subjects who discontinue from the clinical investigation.

4.6 LOST TO FOLLOW-UP

Subjects who miss at least two consecutive visits, as defined by the visit windows and cannot be contacted, may be considered lost to follow-up. All follow-up attempts will be documented and kept with the subject's source documentation, and the applicable eCRFs will be completed.

Subjects that voluntarily withdraw consent after implantation with the HMIOL will be considered Lost to Follow-Up.

4.7 STUDY COMPLETION

ClarVista will notify the Investigators when to contact the IRB / EC to announce study completion at the site.

4.7.1 EARLY STUDY TERMINATION

ClarVista has the right to terminate this study at any time. Reasons for terminating the study may include, but are not limited to, the following:

- The incidence or severity of adverse events in this or any ongoing studies involving the same technology (if applicable), indicates a potential health hazard to subjects
- Subject enrollment is unsatisfactory
- Data recording is inaccurate or incomplete.
- A minimum of 105 subjects has been enrolled in the study *and* a minimum of 44 optic exchanges has taken place.

In the event of premature study termination, appropriate notification will be given to the Investigators, IRB / ECs, and regulatory bodies as applicable. In addition, ClarVista (or designee) will instruct all Investigators to discontinue dispensing study materials or treatments, will ensure all subjects complete appropriate follow-up, and will arrange study closeout visits at each site as appropriate.

4.7.2 STUDY EXTENSION

After the first 25 subjects have reached the 3 month time point (and every 25 subjects thereafter), subject accountability and the rate of optic exchanges will be evaluated, and the enrollment goal will be reevaluated with respect to achieving the necessary sample size.

4.8 CONCOMITANT THERAPIES

4.8.1 CONCOMITANT MEDICATION

Concomitant medications are any prescription drugs used by a subject until conclusion of study participation. Any medication the Investigator deems in the best interest of the subject, is acceptable to prescribe or administer. However, any and all are to be recorded in both the Concomitant Medication source document and eCRF as well as the reason for use (indication). An AE is to be reported and/or recorded as appropriate (see Section 6.0).

4.8.2 CONCOMITANT PROCEDURES

A concomitant procedure is any invasive or non-invasive ocular or peri-ocular procedure that takes place during study participation and will be captured in both the Concomitant Procedure Source Document and eCRF. The following are examples of two such procedures:

- Any PO surgical adjustments to Fellow Eye (i.e. corneal refractive surgery, lens exchange, etc.
- Neodymium: Yttrium-aluminum-garnet (Nd:YAG) procedure to treat Posterior Capsule Opacification (PCO), if necessary. This will be listed as "Nd:YAG Capsulotomy."

Note: Any Nd:YAG capsulotomy procedures prior to exit will be performed only in response to spontaneous subject complaints (i.e. not solicited by study personnel) of reduced Visual Acuity (VA) or glare that affects functional vision, which is associated with PCO or striae, and captured on the eCRF in SLE findings.

An AE is to be reported and/or recorded as appropriate (see Section 6.0). Any procedure reported in the Concomitant Procedure eCRF must have a corresponding Indication listed in either the Ocular History or AE eCRF *(Only exception: PCO – See Section 6.1 for further details)*.

4.9 PROTOCOL DEVIATIONS

All protocol deviations, the date of deviation, and reason will be documented in the Source Document and eCRF. All deviations will be categorized as either major or minor in the following manner:

Major:

- Deviations impacting subject safety
- Deviations impacting subject rights
- Deviations impacting data integrity

Minor:

- All other deviations (e.g. out of window visits, missed data point, etc.)

All major deviations must be reported by the Investigator to the Sponsor and IRB/EC immediately. Subject assessments will continue per protocol for the duration of planned participation unless the deviations put the subject at risk or the subject's condition requires that he/she be discontinued from the study.

5.0 STUDY MATERIALS

5.1 DESCRIPTION OF TEST ARTICLE

The HARMONI™ Modular Intraocular Lens (HMIOL) System is an investigational device designed to allow safe exchange or adjustment of an IOL optic after implantation. [redacted]

The optic component is available in 16 D to 26 D Spherical Equivalent (SE) powers in 0.50D increments. All components are sterilized using ethylene oxide (EtO) and has a shelf life 1 year from the date of sterilization.

[redacted]

[redacted]

5.1.1 INSTRUCTIONS FOR USE – STUDY EYE

Refer to the Surgical Guide for all use and administration details.

5.2 FELLOW EYE INTRAOCULAR LENS

Fellow Eyes will be implanted with a commercially available IOL.

5.2.1 INSTRUCTIONS FOR USE – FELLOW EYE

Refer to the appropriate product insert Instructions for Use documents for all use and administration indications, warnings, and limitations for commercially available products. *No "Off-Label" product use will be allowed.*

5.3 PACKAGING AND LABELING

All packaging and labeling will be consistent with the current study design. The labeling will include at a minimum, the following:

- Sponsor name and address
- Study number
- "For Single Use Only" statement (or equivalent symbol)
- "Investigational Device" caution statement
- Sterility symbol
- Storage temperature range requirements or equivalent (e.g. "Store at room temperature.")
- Expiration date
- Power designation
- Unique serial number
- Model number

5.4 ACCOUNTABILITY

The Investigator is responsible for keeping accurate accountability records of the number of study lenses received, dispensed, and returned to Sponsor. The study lenses must be stored under the appropriate conditions in a secure area and are to be implanted only in subjects enrolled in the study, in accordance with the conditions specified in this protocol.

All accountability records will include the following:

- Model and serial numbers

- Receipt date
- Quantities received
- Initials (attributability) of site personnel who received, dispensed, or returned study lenses
- Date of use
- Subject treated with the study lens (by Subject ID and Initials only)
- Date returned to Sponsor
- Defective or damaged study devices

Periodically throughout the study and/or upon completion, the Sponsor (or designee) will review and verify the Investigator's accountability records. Following verification, and as directed by the Sponsor, all unused and explanted products must be returned to the Sponsor.

***Note:** In addition, any study lenses or components deemed defective, damaged, malfunctioning, or explanted must be retained by the site and returned to the Sponsor for evaluation. Under no circumstances are any components to be discarded or otherwise disposed of. If there is any question as to the applicability of this directive, consult the Protocol Contacts page of this protocol and discuss the situation with a Sponsor representative.*

5.5 OTHER MATERIALS

Additional materials can be provided to sites for the duration of the study on an as-needed basis and may include:

- ETDRS light box, glare source, and charts to perform the standardized VA assessments described in the Manual of Procedures
- Medicel injectors (for study lens injection only)
- IOL micro-incision cutter and forceps
- 40 cm measuring tool to perform near vision testing
- Konan Specular Microscope
- Pentacam Anterior Segment Imaging System

6.0 ADVERSE EVENTS

Safety assessments include adverse events/serious adverse events, and adverse device events. The reporting time period is from the time of consent through the last study visit (12 Month Visit post-primary cataract extraction for Cohort 1 and post-optic exchange for Cohort 2).

6.1 DEFINITIONS

6.1.1 ADVERSE EVENT (AE)

An AE is any untoward medical event in a subject that does not necessarily have a causal relationship to the study device or protocol. AEs include Adverse Device Effects (ADEs). Conditions or diseases that are chronic but stable should not be recorded on AE pages of the eCRF. Similarly, changes in a chronic condition of disease that are consistent with natural disease progression are NOT adverse events and also should not be recorded on the AE pages of the eCRF.

Refer to Section 6.3.1 for instructions regarding events that require expedited reporting to the Sponsor and IRB/EC.

Experience with cataract surgery and the implantation of IOLs has shown that some conditions can be considered normal or expected events following these procedures. The following may be considered normal or expected events after cataract surgery and only need to be reported as AEs as specified here:

- Iritis (cell / flare) – if treated
- Persistent Corneal Stroma Edema (if present at 1 Month)
- Increased IOP only if medical/surgical intervention is required (i.e. medication, paracentesis manipulation)
- VA decrease of 10 or more letters (2 lines) from any previous visit not secondary to any underlying condition
- Any expected post-operative ocular event requiring a change in standard postoperative medication regimen

Note: PCO is not to be reported as an AE, as per ISO 11979-7:2014.

Particular attention should be paid to ensure timely and accurate reporting of any of the following cataract surgery related events:

- Endophthalmitis
- Capsular injury
- Vitreous loss
- Macular edema
- Retinal detachment
- Lens dislocation
- Moderate to severe corneal edema
- Pupillary block / angle closure
- Hypopyon or hyphema

6.1.2 ADVERSE DEVICE EFFECT (ADE)

An ADE is any untoward or unintended effect, event, or response surrounding and with a causal relationship with the use of a medical device. This definition may include any event resulting from insufficiencies or inadequacies in the instructions for use or the deployment of the device or other device malfunctions. This definition includes any event that is a result of a user error and any event that affects a user of the device (i.e. caregiver, bystander, etc).

6.1.3 UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

A UADE is any ADE, which is unanticipated and poses a risk to 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 (see Investigator Brochure [IB]). UADEs also include any unanticipated sight-threatening events and any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

6.1.4 DEVICE DEFICIENCIES (DD)

A Device Deficiency (DD) is a failure of the device to meet its performance specifications or expectations, or otherwise not perform as intended. This can include either a malfunction or damage to the device or any part thereof, regardless of the source of malfunction or damage, including user error, and regardless of the presence of injury (or lack thereof) to subject, user, or bystander.

6.2 AE EVALUATION

AEs experienced in this study may be associated with the study device (i.e. ADE) or the study protocol as demonstrated in the following non-exhaustive list of examples:

Study Device (ADE)

- IOL dislocation
- Explant due to haptic break/damage
- Explant due to base and/or optic damage

Study Protocol

- Allergic reaction to dilating drops
- Lens remnants following surgery
- Capsular tear during surgery to implant study device

6.2.1 EVALUATION

All AEs will be evaluated for and by the following criteria:

- Classification (SAE, AE, ADE or combination)
- Diagnosis (or description if ADE)
- Severity
- Relationship (Causality) to study protocol or device
- Outcome
- Treatment or action taken

6.2.1.1 CLASSIFICATION

When evaluating AEs, the Investigator must determine if the event is serious using the following guidelines:

A **Serious Adverse Event (SAE)** is any AE (ocular or non-ocular) that:

- results in death
- results in serious injury, defined as:
  - life-threatening
  - permanent impairment of a body function (e.g. blindness) or structure
  - necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure, or
  - results in a potentially sight-threatening condition

- is a malfunction that might cause or contribute to a serious injury or death if it were to recur
- requires in-patient hospitalization or prolongation of existing hospitalization*, or
- leads to fetal distress, fetal health, a congenital abnormality, or birth defect

* Hospitalization is a criterion for assessment of seriousness. Hospitalization in the absence of a medical AE is not in itself an AE. For example, the following reports of hospitalization without a medical AE should not be considered either serious or an AE:

- admission for treatment of a pre-existing condition not associated with the development of a new AE or with worsening of the pre-existing condition (e.g. for work-up of persistent pretreatment lab abnormality)
- social admission (e.g. subject has no place to sleep)
- administrative admission (e.g. for yearly physical exam)
- optional admission not associated with a worsening of a pre-existing condition (e.g. elective cosmetic surgery or elective surgery for pre-existing repair of the Achilles tendon [which had not worsened while on study])
- hospitalization for admission without a medical AE

NOTE: For the purposes of this protocol, any UADE will be considered an SAE.

6.2.1.2 DIAGNOSIS OR DESCRIPTION

In all instances, it is preferable to report all AEs and SAEs by diagnosis rather than a sign or symptom if possible. This may necessitate the revision of a previously reported AE or SAE as more information is obtained.

6.2.1.3 SEVERITY

When evaluating AEs, the Investigator must determine the severity of symptoms using the following guidelines:

- Mild: Subject awareness of a sign or symptom that is easily tolerated, requires no treatment, and does not interfere with the subject's daily activities
- Moderate: Subject awareness of a sign or symptom which may be a low level of concern to the subject and may interfere with daily activities, but can be relieved by simple therapeutic care
- Severe: A sign or symptom that interrupts the subject's daily activity and requires systemic therapy or other treatment

6.2.1.4 RELATIONSHIP (CAUSALITY) TO STUDY DEVICE OR STUDY PROTOCOL

When evaluating AEs, the Investigator must evaluate the relationship of the event to the study device and study protocol, using the following guidelines:

- Not Related: AEs which are clearly and incontrovertibly due to causes other than the study device or study protocol (e.g. concomitant disease, etc)
- Related: AEs which are felt with a reasonable degree of certainty to be related to the study device or study protocol

- Unknown: Adverse events for which a connection with the study device or study protocol cannot be ruled-out with certainty, or not enough information is available to assess the relationship

6.2.1.5 OUTCOME

The clinical outcome of an AE will be categorized as follows:

- Resolved without sequellae
- Resolved with sequellae (specify)
- Ongoing (i.e. continuing at time of study discontinuation)
- Death

6.2.1.6 TREATMENT OR ACTION TAKEN

Treatment or Action Taken will be categorized as follows:

- None
- Medical Intervention (specify on Concomitant Medication Source and eCRF)
- Surgical Intervention (specify on Concomitant Procedure Source and eCRF)
- Other (specify)

6.3 REPORTING

6.3.1 ON-SITE EXPEDITED REPORTING

The Investigator is obligated to report the following to the Sponsor within 24 hours of becoming aware of the event to ensure the safety of all participants in the study and to meet regulatory reporting requirements:

- All SAEs, regardless of relationship to study device or study protocol utilizing the SAE/ADE Report Form
- All AEs determined to be related to the study device (ADEs or UADEs) utilizing the SAE/ADE Report Form
- All HMIOL explants (consult Medical Monitor listed on Protocol Contacts page prior to explant, if possible)
- All Device Deficiencies (DD) utilizing the DD Report Form

Refer to the Protocol Contacts page for appropriate Sponsor contact to report the above events.

NOTE: Any explanted HMIOL devices, exchanged HMIOL optics, or any components of the HMIOL System presenting a deficiency or malfunction are to be retained by the site until collected by the Sponsor. Under no circumstances are they to be destroyed or otherwise discarded.

When reporting these events to the Sponsor, the site should forward any supporting documents along with the appropriate reporting form and complete the corresponding eCRF, if applicable. Sites must also report applicable events to the reviewing IRB/EC per its established reporting procedures.

6.3.2 OFF-SITE SAE REPORTING

As a multicenter clinical trial, the Investigators may receive "off-site" reports (e.g. an SAE Report). These are Sponsor reports of SAEs which occurred at other sites for the same trial, or in different trials using the same test article, that met the criteria for reporting. These should be reported to the reviewing IRB per their established reporting procedures.

6.3.3 REPORTING OF COMPLAINTS FOR ANCILLARY MARKETED PRODUCTS

Any complaints, malfunctions or similar events related to ancillary marketed products used in this study should be reported by the Investigators in accordance with the reference information provided on the associated commercial packaging.

6.3.4 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS AT SUBJECT EXIT

Ongoing SAEs and ADEs will be followed until resolution or no further change in the condition is expected. Non-serious AEs that are ongoing at study exit visit or upon discontinuation from the study will be followed per the Investigator's standard of care. Documentation in the eCRF of this follow-up is not required although subject care should continue as appropriate.

6.4 SAFETY MONITORING AND REVIEW

All reported AEs will be reviewed on a weekly basis and assessed for trending and causality to study device or procedure. ADEs, UADEs, DDs, and SAEs will be reviewed upon receipt of expedited reporting (Section 6.3.1). Any unexpected trends or events will necessitate careful review and assessment of any change in the risks associated with participation or study continuation.

If an event occurs affecting a subject's risk of participation, Off-Site Reporting (Section 6.3.2) will be utilized to update sites and the IRB(s) / EC(s). If the safety profile of the event provides for the continuation of the study, Informed Consent Forms will be revised as necessary to ensure subjects' consent to continue participation given the known revised risks.

As outlined in Section 4.7.1, the Sponsor reserves the right to discontinue enrollment at any time.

7.0 CLINICAL ENDPOINTS

7.1 SAFETY ENDPOINTS

Safety will be evaluated by assessing the following:

All HMIOL Eyes Cohort:

- [redacted]
- AE rates as compared to ISO 11979-7:2014 Annex B SPE tables
- [redacted]
- SSI

HMIOL Cohort 1

- [redacted]
- AE rates as compared to ISO 11979-7:2014 Annex B SPE tables
- [redacted]
- SSI

HMIOL Cohort 2

- [redacted]
- AE rates as compared to ISO 11979-7:2014 Annex B SPE tables
- [redacted]
- SSI (planned Optic Exchanged procedures excluded)

7.2 EFFECTIVENESS ENDPOINTS

All HMIOL Eyes Cohort:

- Percent of eyes with post-operative BCDVA 20/40 or better by study Visit
- Percent of eyes that achieve MRSE of ±0.50 D of target by study visit
- Percent of eyes that achieve MRSE of ±1.00 D of target by study visit
- BCDVA by study visit
- UCDVA by study visit
- mBCDVA (with glare) by study visit

HMIOL Cohort 1

- Percent of eyes with post-operative BCDVA 20/40 or better by study visit
- Percent of eyes that achieve MRSE of ±0.50 D of target by study visit
- Percent of eyes that achieve MRSE of ±1.00 D of target by study visit
- BCDVA by study visit
- UCDVA by study visit

HMIOL Cohort 2

- Percent of eyes with post-operative BCDVA 20/40 or better by study visit
- Percent of eyes that achieve UCDVA by post-optic exchange study visit
    - 20/20 or better
    - 20/25 or better
    - 20/32 or better
    - 20/40 or better
    - Worse than 20/40
- Percent of eyes that achieve MRSE of ±0.50 D of optic exchange target by post-optic exchange study visit
- Percent of eyes that achieve MRSE of ±1.00 D of optic exchange target by post-optic exchange study visit
- BCDVA by study visit
- UCDVA by study visit

[redacted]

8.0 STATISTICAL METHODS

This is a feasibility study to evaluate the safety and effectiveness of HMIOL in subjects with primary cataract surgery and subjects with HMIOL optic exchange. In general, the analyses will be provided based on available data. The mean, standard deviation, minimum, and maximum will be prepared for the continuous clinical parameters, and counts and percentages will be presented for the categorical outcomes.

8.1 SAMPLE SIZE CALCULATION

The sample size of this feasibility study is first calculated based on ISO 11979-7:2014 (E) to evaluate the proportion of HMIOL-implanted eyes with BCDVA of 0.3 logMAR or better for All HMIOL Cohort (post optic exchange for HMIOL Cohort 2). The statistical hypotheses for the effectiveness are H0: $p \geq 0.925$ and Ha: $p < 0.925$, where p is the proportion of HMIOL-implanted eye with BCDVA of 0.3 logMAR. The sample size based on the binomial distribution with a one-side significance level of 0.05 and a power at a true p of 0.85. The table below summarizes the sample sizes and the corresponding statistical power. For this feasibility study, a sample size of at least 100 subjects will provide a statistical power of at least 75% to accept the alternative hypothesis of $p < 0.925$ if the true p is 0.85.

Sample Size	Statistical Power
100	0.753
110	0.785
120	0.813
130	0.837
140	0.858
150	0.876
160	0.891
170	0.905

180	0.916
190	0.953
200	0.959

With such sample sizes, the one-sided upper 95% confidence limit of the adverse even rate is summarized in the following table for the adverse events that were not observed during the study.

Sample Size	One-Sided Upper 95% Confidence Limit
100	0.0362
110	0.0330
120	0.0303
130	0.0230
140	0.0260
150	0.0243
160	0.0228
170	0.0215
180	0.0203
190	0.0192
200	0.0183

Therefore, a sample size of 100 to 200 deems to be sufficient for the safety and effectiveness objectives of this feasibility study based on ISO 11979-7. With a drop-out rate of at least 5%, this feasibility study will enroll at least 105 eyes implanted with HMIOL.

[redacted]

[redacted]

[redacted]

It should be noted that this is a feasibility study. All the analyses are to evaluate the effectiveness and safety of the HMIOL for the future confirmatory study. No adjustment is performed for the multiplicity.

8.2 ANALYSES POPULATIONS

Subjects that are screened but disqualified based on the preoperative and intra-operative eligibility criteria will be excluded from the safety and effectiveness data analyses. However, their reasons for the screen failure will be summarized. The analyses populations defined below are defined for the study lens. For the fellow-eye cohort (Cohort 4), data analyses for some selected outcomes (such as [redacted]afety events, UCDVA, and BCDVA) may be performed for eyes with successful IOL implants during surgeries in order to numerically compare to the results of the HMIOL cohorts.

8.2.1 SAFETY POPULATION

The **Safety Population** includes eyes with attempted study lens (HMIOL) implantation, (successful or aborted after contact with the eye). The intraoperative and postoperative AEs and DDs will be summarized based on the safety population.

8.2.2 IMPLANTED-EYE POPULATION

The **Implanted-Eye** Population consists of eyes with successful HMIOL implantations during surgeries. Since it is important to evaluate HMIOL's effect on the study [redacted]slit lamp examination, intraoperative pressure (IOP), and dilated fundus examination (DFE) will be based on the implanted-eye population.

Additionally, the UCDVA, BCDVA, mesopic BCDVA (mBCDVA) with and without glare, MRSE, absolute EPR, and [redacted] will be evaluated based on the implanted-eye population.

8.2.3 PER PROTOCOL POPULATION

The **Per Protocol** (PP) Population contains eyes with successful HMIOL implantations during surgeries and do not have major protocol deviation (such as improperly enrolled in the study or lens power calculation errors) and will be considered the primary population for effectiveness outcomes. The effectiveness outcomes (UCDVA, BCDVA, mBCDVA with and without glare, MRSE, and absolute EPR) will be evaluated based on the per protocol population.

The protocol deviations will be determined reviewed by ClarVista clinical personnel prior to analysis.

8.2.4 BEST-CASE POPULATION

The **Best Case** population is the PP population with all of the following characteristics:

- No clinically significant preoperative ocular pathology in the study eye, including any of the following present at the preoperative visit
  - Pseudoexfoliation
  - Glaucoma
  - Uveitis
  - Retinal detachment

- Diabetic retinopathy
- Macular degeneration
- Amblyopia
- Others as specified by unmasked sponsor clinical personnel after a review of the adverse events present at the preoperative visit

- No macular degeneration detected at any time in the study eye
- No previous surgery for the correction of refractive errors in the study eye

The purpose of the Best Case population is to evaluate BCDVA as described in ISO 11979-7:2014.

8.3 STATISTICAL METHODS

The data analyses will be based on the analysis populations described above. No imputation for missing data will be performed. The statistical summaries will be prepared for HMIOL Cohort 1, HMIOL Cohort 2, and HMIOL eye Cohort (Cohort 1 + Cohort 2). For some selected outcomes, the summaries will be prepared for the fellow eye cohort.

8.3.1 SAFETY OUTCOMES

8.3.1.1 ADVERSE EVENTS AND DEVICE DEFICIENCIES

Adverse events and device deficiencies will be summarized at each study visit based on the safety population for Cohort 1 and Cohort 2. The number and percentage of eyes reported with the ISO specified 12-month cumulative and persistent adverse events will be calculated for Cohort 1 and Cohort 2 separately. Additionally the events will be summarized for the HMIOL cohort (12-months after primary cataract surgery for Cohort 1 and 12-month after HMIOL optic exchange for Cohort 2). The corresponding one-sided lower 95% confidence limit will be calculated based on the binomial distribution and compared to the ISO SPE rate. If the one-sided lower 95% confidence limit is smaller than the SPE rate specified by ISO, then the null hypothesis of event rate of less than the SPE rate will not be rejected. [redacted]

The ISO cumulative and persistent adverse events will also be provided for the fellow eye cohort and numerically compared to those of HMIOL eye cohort.

Additionally, the number and percentage of eyes reported with HMIOL-related adverse events during the study will be summarized for HMIOL Cohort 1, HMIOL Cohort 2, and HMIOL-eye Cohort. The two-sided 90% confidence interval of the percentage will also be provided.

8.3.1.2 [redacted]

[redacted]

[redacted]

8.3.1.3 OTHER SAFETY OUTCOMES

Other safety outcomes such as slit lamp examination, dilated fundus examination, and lens stability will be summarized descriptively at each visit based on the implanted-eye population for the HMIOL Cohort 1 and HMIOL Cohort 2. For the preoperative and 3-month post-primary-surgery visits, the descriptive statistics will also be provided for the HMIOL-eye cohort.

8.3.2 EFFECTIVENESS OUTCOMES

The effectiveness outcomes will be analyzed based on the Implanted-eye Population and PP Population. The BCDVA will also be summarized based on the Best-case population as suggested by ISO. [redacted]

8.3.2.1 BCDVA

The LogMAR will be derived for BCDVA. The descriptive statistics for continuous variables will be used to summarize LogMAR BCDVA at each visit based on the implanted-eye population for the three different lens cohorts (HMIOL Cohort 1, HMIOL Cohort 2, and Fellow-eye Cohort). The data at preoperative and 3-month post-primary-surgery will also be summarized for the HMIOL-eye cohort.

Additionally, the number and percentage of eyes reaching BCDVA 20/40 or better at each visit will be prepared for Cohort 1, Cohort 2, and the Fellow-eye Cohort. The one-sided upper 95% confidence limit of the proportion of HMIOL eyes with 20/40 or better will be calculated based on the binomial distribution and compared to a target of 0.925. If the confidence limit is > 0.925, then the null hypothesis of $p \geq 0.925$ will not be rejected.

The analyses will be repeated based on the Per Protocol Population and the Best-case Population.

8.3.2.2 MBCDVA

The descriptive statistics for continuous variables will be used to summarize LogMAR mBCDVA with and without glare at 3-month post-primary-surgery visit based on the implanted-eye population for the HMIOL-eye Cohort.

8.3.2.3 UCDVA

The LogMAR will be derived for UCDVA. The change in the LogMAR UCDVA from pre-optic exchange to post-optic exchange will be calculated for each of the HMIOL Cohort 2 eyes. The change will be summarized descriptively with the 95% confidence interval of the mean change at each post-optic exchange visit. The proportion of eyes with UCDVA of 20/20 or better, 20/25 or better, 20/32 or better, 20/40 or better, and

worse than 20/40 at each visit will be summarized for the HMIOL Cohort 2 at pre-exchange and every post-exchange visit. The difference in the proportions will be compared by McNemar test.

8.3.2.4 ERROR PREDICTED REFRACTION (EPR)

The error predicted refraction (EPR) will be calculated for each treated eye as follows:

EPR = Postoperative MRSE adjusted to 6 meters – TRRE (target residual refractive error)

Then the absolute value of EPR will be derived. The means, standard deviations, minimum, and maximum of absolute EPR at each visit will be provided for all three lens cohort based on Implanted-eye Population. Additionally, the number and percentage of eyes with an EPR within ±0.50 D of target and of ±1.00 D of target will be derived for each postoperative visit.

For the HMIOL-eye Cohort and HMIOL Cohort 1, the difference in the absolute EPR between the HMIOL eye and its fellow eye at the same postoperative visits will be calculated for each subject. The mean, standard deviation, minimum, and maximum of the difference will be derived along with the 95% confidence interval of the mean difference.

For the HMIOL Cohort 2, the difference in the absolute EPR will be compared to the 3 month pre exchange EPR for the same eye at all postoperative visits. The mean, standard deviation, minimum, and maximum of the difference will be derived along with the 95% confidence interval of the mean difference.

[redacted]

9.0 DATA MANAGEMENT

9.1 DATA QUALITY ASSURANCE

All requested information must be entered on the eCRF and confirmable through source documentation. If an item is not available or not applicable, this fact should be clearly indicated.

Data will be entered into a computer database developed specifically for this trial. During the course of the trial, data queries will be generated for data points that are potentially erroneous and require appropriate clarification or correction.

9.1.1 DATA MONITORING

Periodic monitoring (either remote and/or on-site) will take place to ensure data integrity. Study monitoring involves the following elements:

ClarVista personnel, or designee, may meet with investigators prior to the initiation of the study in order to review the adequacy of the subject population, facilities, and equipment with respect to the needs of the study, and to familiarize the investigator and support staff with the study protocol.

ClarVista personnel, or designee, may meet with the investigators at the time enrollment is initiated in order to ensure that subjects are being properly selected, that the methods described in the study protocol are thoroughly understood by the investigator, and that study data are being correctly recorded.

ClarVista personnel, or designee, may visit the clinical site at any time during the course of the study to review and/or collect completed case report forms. Additionally, telephone consultation will occur as necessary during the course of the study to ensure the proper progress and documentation of the study findings.

The study data will be carefully protected, and masking utilized to the extent possible, in order to prevent bias.

9.2 RECORD RETENTION

The investigator shall maintain all subject records for whichever of the following periods is shorter:

- A period of two years after the date on which FDA approves the marketing of the device
- A period of five years after the date on which the results of the study are submitted to the FDA in support of the marketing of the device

OR

- A period equal to the minimum required by the regional authority.

The Investigator / Site must contact ClarVista as provided in the Protocol Contacts page prior to discarding or disposing of any study related supplies or documents. The Sponsor retains the right to have all study documents shipped (at Sponsor's expense) for archival purposes, as an alternative to disposal.

10.0 REFERENCES

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APPENDIX A – TABLE 1: SCHEDULE OF ASSESSMENTS – HMIOL & COHORT 1

Table 1	All HMIOL Cohort							Optic Exchange Window (3 Mo Visit +1-21 Days)	Cohort 1	
Procedure/Assessments	Pre-Op Visit[2] Day -90 to -0	Op Visit 1 Day 0	Form 1 1 Day Visit (Day 1-2)	Form 2 1 Wk Visit (Day 7-14)	Fellow Eye Implant Window (Day 0 +7-30 Days)	Form 3 1 Mo Visit (Day 30-60)	Form 4 3 Mo Visit (Day 80-100)		Form 5 6 Mo Visit (Day 120-180)	Form 6 12 Mo Visit (Day 330 - 420)
Informed Consent	X			X[3]			X[10]			
Demographics	X									
Med/Ophthalmic History	X	X								
Eligibility[4]	X	X					X[10]			
UCDVA[5]			X	X		X	X		X	X
[redacted]			[redacted]	[redacted]		[redacted]	[redacted]		[redacted]	[redacted]
Manifest Refraction	X			X		X	X		X	X
BCDVA	X			X		X	X		X	X
[redacted]							[redacted]		[redacted]	[redacted]
mBCDVA							X			
Dominant Eye	X									
Keratometry [6]	X					X	X			X
Axial Length	X					X	X			X
Anterior Chamber Depth [7]	X									
[redacted]			[redacted]	[redacted]		[redacted]	[redacted]		[redacted]	[redacted]
IOL Power Calculation [9]	X						X[10]			
Slit Lamp Examination	X		X	X		X	X		X	X
[redacted]							[redacted]		[redacted]	[redacted]
Pachymetry [8]	X					X	X		X	X
IOP	X		X	X		X	X		X	X
Pupil Size	X									
Lens Assessment	X									
Capsule Assessment [11]									X	X
[redacted]			[redacted]	[redacted]		[redacted]	[redacted]			[redacted]
[redacted]			[redacted]	[redacted]		[redacted]	[redacted]			[redacted]
[redacted]		[redacted]	[redacted]	[redacted]		[redacted]	[redacted]		[redacted]	[redacted]
Dilated Fundus Exam	X						X			X
Primary Surgery (HMIOL)		X								
Fellow Eye Surgery (see Table 2)										
Optic Exchange (see Table 3)										

[2] Assessments are to be completed for both eyes
[3] Fellow Eye Consent - SOC
[4] To include Urine Pregnancy Test if applicable
[5] If UCDVA is < 20/40, perform Pinhole (PH) vision
[6] Measurements via biometry will be utilized for both calculations and data capture
[7] Measurement via biometry will be utilized for calculations
[8] Measurement via Pentacam and submitted for assessment by the Reading Center
[9] To be reviewed and approved by the Sponsor
[10] Only for those subjects with planned Optic Exchange
[redacted]

APPENDIX A – TABLE 2: SCHEDULE OF ASSESSMENTS – FELLOW EYE

Table 2	Fellow Eye Cohort						
Procedure/Assessments	Op-Visit 2 Fellow Eye Implant (Day 0 +7-30 Days)	Form 1.1 FE 1 Day Visit (Day 1-2)	Form 2.1 FE 1 Wk Visit (Day 7-14)	Form 3.1 FE 1 Mo Visit (Day 30-60)	Form 4.1 FE 3 Mo Visit (Day 80-100)	Form 5.1 FE 6 Mo Visit (Day 120-180)	Form 6.1 FE 12 Mo Visit (Day 330 - 420)
Eligibility	X						
UCDVA		X	X	X	X	X	X
Manifest Refraction				X	X		X
BCDVA				X	X		X
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]					X	X	X
Capsule Assessment						[redacted]	[redacted]
Dilated Fundus Exam					X		X
Fellow Eye Surgery	X						

APPENDIX A – TABLE 3: SCHEDULE OF ASSESSMENTS – COHORT 2

Table 3	Cohort 2 - Optic Exchange Complete						
Procedure/Assessments	Op-Visit 3 Optic Exchange Visit (3 Mo Visit +1-21 Days)	Form 1.2 OE 1 Day Visit (Day 1-2)	Form 2.2 OE 1 Wk Visit (Day 7-14)	Form 3.2 OE 1 Mo Visit (Day 30-60)	Form 4 2 OE 3 Mo Visit (Day 80-100)	Form 5.2 OE 6 Mo Visit (Day 120-180)	Form 6 2 OE 12 Mo Visit (Day 330 - 420)
Eligibility	X						
UCDVA[13]		X	X	X	X	X	X
Manifest Refraction			X	X	X	X	X
BCDVA			X	X	X	X	X
Keratometry [14]				X	X		X
Axial Length				X	X		X
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Slit Lamp Examination		X	X	X	X	X	X
[redacted]					[redacted]	[redacted]	[redacted]
[redacted]				[redacted]	[redacted]	[redacted]	[redacted]
IOP		X	X	X	X	X	X
Lens / Capsule Assessment [15]					X	X	X
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]		[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]		[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Dilated Fundus Exam					X		X
Optic Exchange Procedure	X						

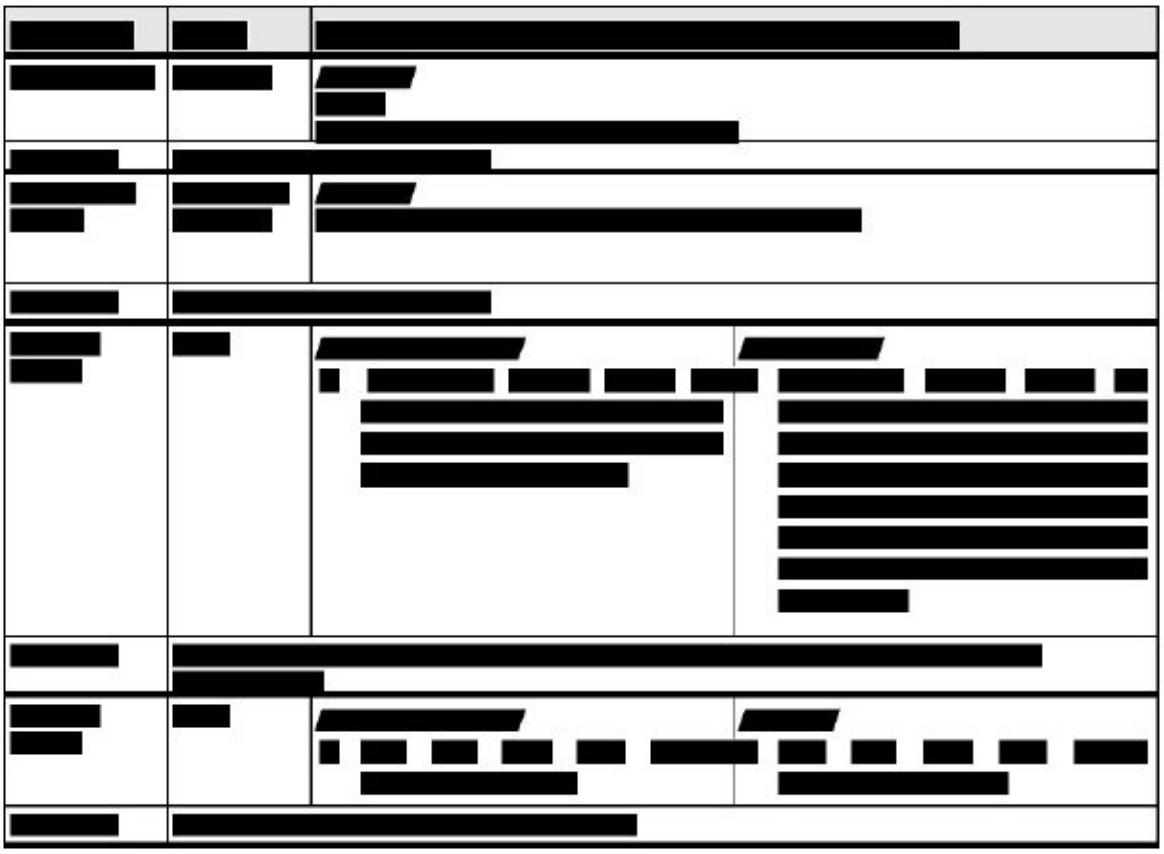
[13] If UCDVA is <20/40, perform Pinhole (PH) vision
[14] Measurements via biometry
[redacted]

[redacted]

Printed By: Print Date:

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	

[redacted]



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of clinical value

Date/Time (mm/dd/yyyy GMT):	Signed by:	Justification:
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]