Johnson & Johnson Vision Care, Inc.

Clinical Study Protocol

Handling Evaluation of Multifocal Toric Contact Lenses

Protocol CR-5935

Version: 3.0 Amendment 2

Date: 31-MAY-2017

Investigational Products: JJVC Investigational etafilcon A Multifocal Toric Contact Lens

Key Words: Presbyopia, Astigmatism, Multifocal, Etafilcon A, Daily Wear, Non-Dispensing

Statement of Compliance to protocol, GCP and applicable regulatory guidelines:
This trial will be conducted in compliance with the protocol, the International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP), ISO 14155, the Declaration of Helsinki, and all applicable regulatory requirements.

TABLE OF CONTENTS

LISTING OF TABLES

LISTING OF FIGURES

PROTOCOL TITLE, NUMBER, VERSION
Title: Handling Evaluation of Multifocal Toric Contact Lenses

Protocol Number: CR-5935
Version: 3.0 Amendment 1
Date: 31-MAY-2017

SPONSOR NAME AND ADDRESS

Johnson & Johnson Vision Care, Inc. (JJVC)
7500 Centurion Parkway,
Jacksonville, FL 32256

MEDICAL MONITOR

Name: Thomas R. Karkkainen, OD, MS, FAAO

Title: Sr. Principal Research Optometrist
Address: 7500 Centurion Parkway, Jacksonville, Florida 32256
[redacted]
Email: TKarkkai@its.jnj.com

The Medical Monitor must be notified by the clinical institution/site by e-mail, fax, or telephone within 24 hours of learning of a Serious Adverse Event. The Medical Monitor may be contacted during business hours for adverse event questions. General study related questions should be directed towards your assigned clinical research associate.

The Medical Monitoring Plan is maintained as a separate document and included in the Trial Master File.

AUTHORIZED SIGNATURES

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations, ICH guidelines, ISO 14155 and the Declaration of Helsinki.

Author	**See Electronic Signature Report** Thomas R. Karkkainen Sr. Principal Research Optometrist	DATE
Clinical Operations Manager	**See Electronic Signature Report** [redacted]	DATE
Biostatistician	**See Electronic Signature Report** [redacted]	DATE
Data Management	**See Electronic Signature Report** [redacted]	DATE
Reviewer	**See Electronic Signature Report** Fellow Review Not Required	DATE
Approver	**See Electronic Signature Report** [redacted]	DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	Tom Karkkainen	Original Protocol	09-May-2017
2.0	Tom Karkkainen	-Updated Flow Chart Refraction Sphere powers to -1.50 D to -4.50 D and added Near Add Determination to Baseline. -Synopsis, Inclusion #5 Removed the double minus (-) sign. -Synopsis, Inclusion # 9: Replaced "of" with "or". -Commonly used abbreviations section: Added additional abbreviations. -Section 1.2: Removed the double minus (-) sign. -Section 3.2 Inclusion # 9: Replaced "of" with "or". -Section 7.1, Table 3: Added Near Add Determination to the Time and Events Table. -Section 7.2, Detailed Study Procedures: Added Near Add Determination step (step 1.12). -Final Evaluation: added verbiage stating if subject is a screen failure and the procedures in the final evaluation were just completed, they do not need to be repeated. Updated Date and version throughout the Document	25-May-2017
3.0	Tom Karkkainen	-Synopsis Trial Registration-Study will be registered to ClinicalTrials.gov -Appendix B – Patient Instruction Guide v2.0	31-May-2017

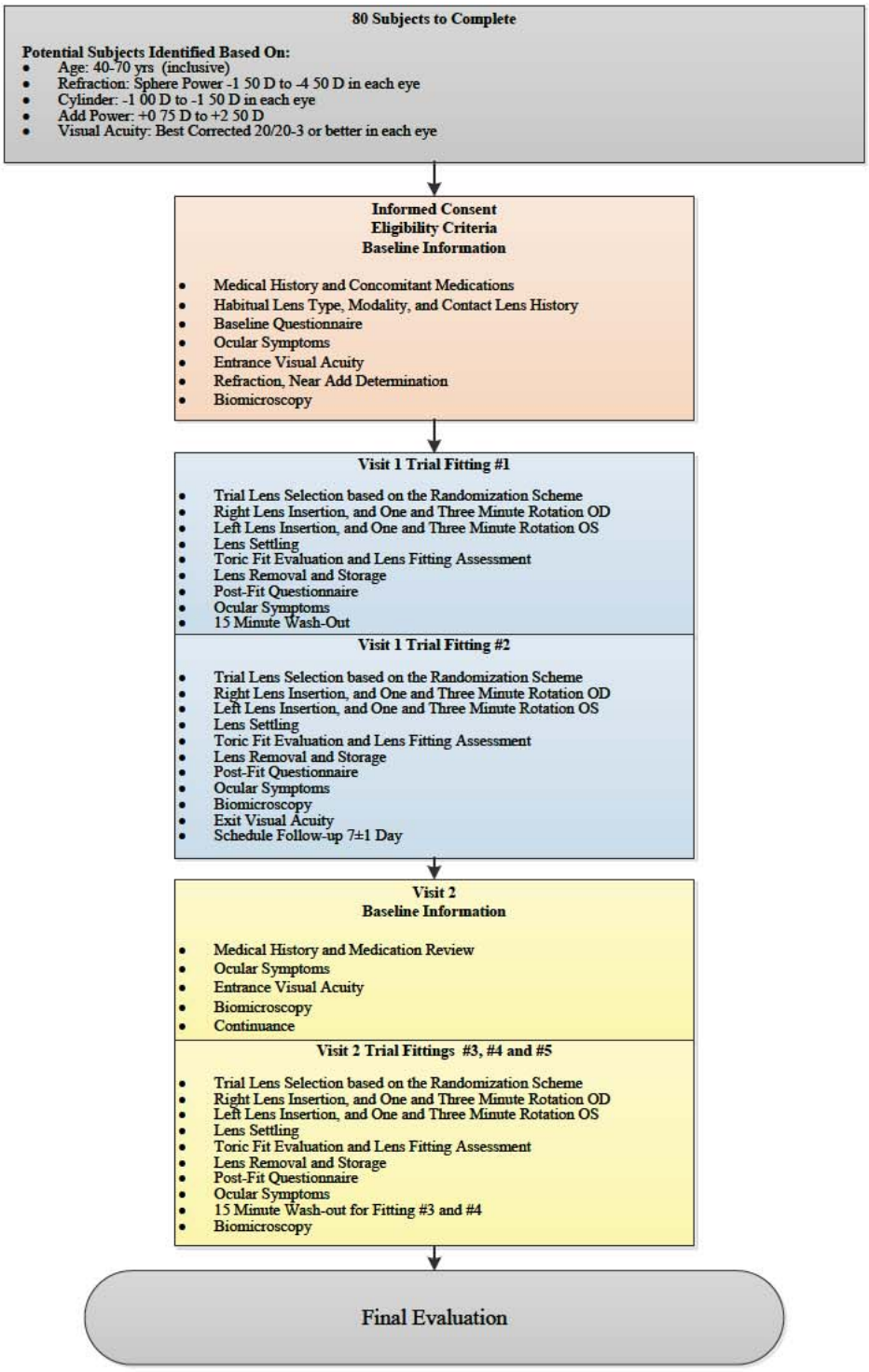
SYNOPSIS

Protocol Title	Handling Evaluation of Multifocal Toric Contact Lenses
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Development phase, Phase 1
Trial Registration	This study will be registered on ClinicalTrials.gov.
Test Article(s)	Investigational Products: JJVC Investigational Multifocal Toric Contact Lens manufactured in etafilcon A material in varying thicknesses.
Wear and Replacement Schedules	Wear Schedule: The lenses will be used on a daily wear basis and just worn while in the clinic. Replacement Schedule: There is no planned replacement as the study is non-dispensing.
Objectives	This study is an initial evaluation of subject responses to the handling of a JJVC Investigational etafilcon A Toric Multifocal Contact Lenses in varying thicknesses.
Study Endpoints	Primary endpoint: Subjective responses for handling using the CLUE questionnaire. The secondary endpoint will be lens fitting.
Study Design	This is a double-masked, bilateral, randomized, non-dispensing clinical trial. The subjects will wear each pair of lenses for approximately 15 minutes with a 15-minute wash-out between each pair. A total of 2 pairs of lenses will be fit at the first visit and 3 at the second visit. Lens Stability and Lens fit will be assessed for each pair. See the flow chart at the end of the synopsis table for the schematic of the study visits and procedures of main observations.
Sample Size	A total of approximately 100 eligible subjects will be enrolled with 80 targeted to complete.
Study Duration	The study will last approximately 4 weeks.
Anticipated Study Population	Healthy male and female volunteers who are presbyopic astigmats who have myopia and are adapted contact lens wearers currently wearing contact lenses in both eyes.

Eligibility Criteria	Potential subjects must satisfy all of the following criteria to be enrolled in the study 1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form 2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol 3. The subject must be between 40 and 70 years of age. 4. The subject's distance refraction must be in the range of -1.50 to -4.50 5. The subject's refractive cylinder must be -1.00 to -1.50 D in each eye 6. The subject's ADD power must be in the range of +0.75 D to +2.50 D in each eye 7. The subject must have best corrected visual acuity of $20/20^{-3}$ or better in each eye. 8. Subjects must own a wearable pair of spectacles if required for their distance vision. 9. The subject must be an adapted soft contact lens wearer in both eyes (ie, worn lenses a minimum of 2 days per week for at least 8 hours per wear day, for 1 month or more duration) 10. The subject must already be wearing a presbyopic contact lens correction (eg, reading spectacles over contact lenses, multifocal or monovision contact lenses, etc) or if not respond positively to at least one symptom on the "Presbyopic Symptoms Questionnaire". Potential subjects who meet any of the following criteria will be excluded from participating in the study: 1. Ocular or systemic allergies or disease, or use of medication which might interfere with contact lens wear 2. Pregnancy or lactation 3. Currently diagnosed with diabetes 4. Infectious diseases (eg, hepatitis, tuberculosis) or an immune-suppressive disease (eg, HIV). 5. Clinically significant (Grade 3 or 4) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities or bulbar injection, or any other corneal or ocular abnormalities which would contraindicate contact lens wear 6. Entropion, ectropion, extrusions, chalazia, recurrent styes, dry eye, glaucoma, history of recurrent corneal erosions 7. Any previous, or planned, ocular or intraocular surgery (eg, radial keratotomy, PRK, LASIK, lid procedures, cataract surgery, retinal surgery, etc) 8. A history of amblyopia, strabismus or binocular vision abnormality

	9. Any ocular infection or inflammation 10. Any ocular abnormality that may interfere with contact lens wear 11. Use of any ocular medication, with the exception of rewetting drops 12. History of herpetic keratitis 13. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment 14. Employee of clinical site (eg, Investigator, Coordinator, Technician).
Disallowed Medications/Interventions	Use of any prescription or over-the-counter (OTC) medications that may affect contact lens wear.
Measurements and Procedures	Subjective responses for handling using the CLUE questionnaire.
Microbiology or Other Laboratory Testing	None
Study Termination	The occurrence of one or more Unanticipated Adverse Device Effect (UADE), or any SAE where relationship to study agent cannot be ruled out, will result in stopping further dispensing investigational product. In the event of a UADE or SAE, the Sponsor Medical Monitor may unmask the treatment regimen of subject(s) and may discuss this with the Principal Investigator before any further subjects are enrolled.
Ancillary Supplies/ Study-Specific Materials	Eye-Cept® Rewetting drops.
Principal Investigator(s) and Study Institution(s)/Site(s)	A full list of Principal Investigators, clinical sites, and institutions is kept separately from the Study Protocol and is included in the study Trial Master File.

Figure 1: Study Flowchart



COMMONLY USED ABBREVIATIONS AND DEFINITIONS OF TERMS

ADD	Plus Power Required For Near Use
ADE	Adverse Device Effect
AE	Adverse Event/Adverse Experience
BCVA	Best Corrected Visual Acuity
BSCVA	Best Spectacle Corrected Visual Acuity
CFR	Code of Federal Regulations
CLUE	Contact Lens User Experience
COAS	Complete Ophthalmic Analysis System
COM	Clinical Operations Manager
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
CT	Center Thickness
[redacted]	[redacted]
D	Diopter
DMC	Data Monitoring Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intent-to-Treat
JJVC	Johnson & Johnson Vision Care, Inc.
LC	Limbus Center
LogMAR	Logarithm of Minimal Angle of Resolution
MedDRA©	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NIH	National Institutes of Health
OD	Right Eye
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
OS	Left Eye
OU	Both Eyes
PD	Protocol Deviation
PHI	Protected Health Information
PI	Principal Investigator
PIG	Patient Instruction Guide

PQC	Product Quality Complaint
PRO	Patient Reported Outcome
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
VA	Visual Acuity
HIV	Human immunodeficiency virus
PRK	Photorefractive keratectomy
LASIK	Laser-assisted in situ keratomileusis
IRT	Item Response Theory
CIE	Corneal infiltrative Event
ILB	Intentionally Left Blank
CLPU	Contact Lens Induced Peripheral
SIE	Significant Infiltrative Events
SEALs	Superior Epithelial Arcuate Lesions
BSCVA	Best Spectacle-Corrected Visual Acuity
EKC	Epidemic Keratoconjunctivitis
MK	Microbial Keratitis
CLPC	Contact Lens Papillary Conjunctivitis
CS	Homogenous compound symmetry
UN	Unstructured covariance structure
AICC	Akaike Information Criteria Corrected
LSM	Least-square means
NSIE	Non-significant Infiltrative Event
SPK	Superficial Punctate Keratitis

1. INTRODUCTION AND BACKGROUND

Johnson & Johnson Vision Care (JJVC) has recently launched a multifocal contact lens, 1-Day ACUVUE Moist Multifocal. The lens is indicated to correct ≤ -0.75 D of refractive cylinder. A significant number of presbyopic eyes have greater than -0.75 D of cylinder. With this in mind, JJVC has a toric multifocal lens development program to attempt to fill this need. The purpose of the current study is to evaluate the impact peripheral thickness has on the handling characteristics of the toric multifocal lens.

1.1. Name and Descriptions of Investigational Products

Investigational Products: Etafilcon A Toric Multifocal Contact Lens

1.2. Intended Use of Investigational Products

The toric lens product is indicated to correct presbyopic eyes that have between -1.00 and -1.50 D of refractive cylinder.

1.3. Summary of Findings from Nonclinical Studies

All previous preclinical findings were deemed satisfactory prior to proceeding with clinical trials on humans. For the most comprehensive nonclinical information regarding the etafilcon-A Toric Multifocal Contact Lens refer to the latest version of the CR-5935 Investigational Brochure.

1.4. Summary of Known Risks and Benefits to Human Subjects

The Investigational Toric Multifocal contact lenses are designed as a continuous asphere with toric correction providing for the correction of refractive ametropia and presbyopia. The lenses have the same stabilization as the marketed 1-DAY ACUVUE® MOIST® for Astigmatism lenses. The material is a hydrogel material, etafilcon-A, which is in the Group 4, high water, ionic polymer family and is used in the 1-DAY ACUVUE® MOIST® brand of products.

The intent of this product is as a daily disposable contact lens that the subject wears while awake. This lens is not intended for reusable or extended wear. This evaluation is for daily disposable modality only. Anticipated risks and adverse reactions with this lens are similar to other soft daily wear contact lenses used to correct presbyopia. A listing of examples of adverse reactions is found in the Section 13 of this protocol. The Investigator should follow normal clinical guidelines in regard to examination and care of subjects who participate in this trial. For the most comprehensive clinical information regarding etafilcon A Toric Multifocal Contact Lens refer to the latest version of the etafilcon A Toric Multifocal Contact Lens Investigator Brochure.

1.5. Relevant Literature References and Prior Clinical Data Relevant to Proposed Clinical Study

A PubMed search using the terms "contact lens handling and thickness" revealed one relevant article to this study. Harris, et. al.[1] studied the impact lens center thickness had on performance. They evaluated two groups of lenses having conventional thicknesses (0.14-0.16 mm) and a third group that were thin (0.04-0.06 mm) that the thin lens group performed less favorably with the main reason for failure being comfort due to poor

centration and arcuate staining and they also noted that lens handling was a major problem for the thinner lenses.

Lenses that have the same nominal design as the Control lenses used in this study have been evaluated in a number of other clinical studies [redacted]. In addition to these studies the same lens design is being evaluated in [redacted] which is ongoing at the time of the writing of this protocol. Details with regards to these studies can be found in the latest version of the Investigator Brochure.

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

This study is an initial evaluation of subject responses to the handling of JJVC Investigational etafilcon A Toric Multifocal Contact Lenses in varying thicknesses.

Primary Objective
The primary objective is to evaluate the handling of a toric multifocal lens of various peripheral thicknesses.

Secondary Objective
Lens fitting characteristics on the eye will be evaluated.

Exploratory Objective
Subjective comfort scores will also be evaluated.

2.2. Endpoints

To evaluate the handling performance of contact lenses in myopic subjects who are habitual soft contact lens wearers. The primary endpoint will be the subjective handling responses.

Primary Endpoint
The primary endpoint is overall lens handling assessed using the Contact Lens User Evaluation questionnaire (CLUE™). CLUE is a validated Patient Reported Outcome (PRO) questionnaire developed to measure general and throughout the day comfort/vision, as well as symptoms of discomfort/poor vision, lens handling and packaging. Derived CLUE scores using Item Response Theory (IRT) follow a normal distribution with a population average score of 60 (SD 20), where higher scores indicate a more favorable/positive response. A 5 point increase in an average CLUE score translates into 10% shift in the distribution of scores for population of soft contact lens wearers.

Secondary Endpoint
Lens fitting.

Other Observation
Subjective Comfort.

2.3. Hypotheses

Primary Hypotheses

1. Test lens #1 (30 microns thicker) handling scores will be non-inferior to the Control lens after approximately 15 minutes of wear. A non-inferiority margin of -5 CLUE points will be used.
2. Test lens #2 (16 microns thinner) handling scores will be non-inferior to the Control lens after approximately 15 minutes of wear. A non-inferiority margin of -5 CLUE points will be used.

If both primary hypotheses are met, the following two secondary hypotheses will be tested.

Secondary Hypotheses

1. Test lens #3 (22 microns thinner) handling scores will be non-inferior to the Control lens after approximately 15 minutes of wear. A non-inferiority margin of -5 CLUE points will be used.
2. Test lens #4 (28 microns thinner) handling scores will be non-inferior to the Control lens after approximately 15 minutes of wear. A non-inferiority margin of -5 CLUE points will be used.

Other Hypotheses
Not Applicable.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

Healthy male and female volunteers who are presbyopic astigmats who have myopia and are adapted contact lens wearers currently wearing contact lenses in both eyes.

3.2. Inclusion Criteria

Potential subjects must satisfy all of the following criteria to be enrolled in the study:

1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form
2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol
3. The subject must be between 40 and 70 years of age.
4. The subject's distance refraction must be in the range of -1.50 D to -4.50 D.
5. The subject's refractive cylinder must be -1.00 to -1.50 D in each eye
6. The subject's ADD power must be in the range of +0.75 D to +2.50 D in each eye
7. The subject must have best corrected visual acuity of $20/20^{-3}$ or better in each eye
8. Subjects must own a wearable pair of spectacles if required for their distance vision
9. The subject must be an adapted soft contact lens wearer in both eyes (ie, worn lenses a minimum of 2 days per week for at least 8 hours per wear day, for 1 month or more duration)
10. The subject must already be wearing a presbyopic contact lens correction (eg, reading spectacles over contact lenses, multifocal or monovision contact lenses, etc) or if not

respond positively to at least one symptom on the "Presbyopic Symptoms Questionnaire".

3.3. Exclusion Criteria

Potential subjects who meet any of the following criteria will be excluded from participating in the study:

1. Ocular or systemic allergies or disease, or use of medication which might interfere with contact lens wear
2. Pregnancy or lactation
3. Currently diagnosed with diabetes
4. Infectious diseases (eg, hepatitis, tuberculosis) or an immune-suppressive disease (eg, HIV)
5. Clinically significant (Grade 3 or 4) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities or bulbar injection, or any other corneal or ocular abnormalities which would contraindicate contact lens wear
6. Entropion, ectropion, extrusions, chalazia, recurrent styes, dry eye, glaucoma, history of recurrent corneal erosions
7. Any previous, or planned, ocular or intraocular surgery (eg,radial keratotomy, PRK, LASIK, lid procedures, cataract surgery, retinal surgery, etc
8. A history of amblyopia, strabismus or binocular vision abnormality
9. Any ocular infection or inflammation
10. Any ocular abnormality that may interfere with contact lens wear
11. Use of any ocular medication, with the exception of rewetting drops
12. History of herpetic keratitis
13. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment
14. Employee of clinical site (eg, Investigator, Coordinator, Technician).

3.4. Enrollment Strategy

Study subjects will be recruited from the potentially eligible subjects identified in the clinical site's subject database.

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This is a double-masked, bilateral, randomized, non-dispensing clinical trial. The subjects will wear each pair of lenses for approximately 15 minutes with a 15 minute wash-out between each pair. A total of 2 pairs of lenses will be fit at the first visit and 3 at the second visit. Lens stability and lens fit will be assessed for each pair. See the flow chart at the end of the synopsis table for the schematic of the study visits and procedures.

4.2. Study Design Rationale

As handling of lenses is subjective measure related to a subject's experience the primary measurement tool selected for the study was a validated PRO questionnaire (CLUE) that can be used to quantify that experience. A crossover design was chosen to help to control for

confounding variables between subjects that may influence the primary outcome. In order to help control for potential carry over effects a washout period is being employed between lens trials and the study will also be randomized. As the lenses have no unique identifiers the subjects as well as the examiners will be masked in an attempt to reduce bias.

4.3. Enrollment Target and Study Duration

Approximately 100 subjects will be enrolled in the study with 80 targeted to complete the cohort. All subjects will have at least -1.00 D to -1.50 D of refractive cylinder in both eyes. The study will take place at several clinical sites and have two study visits per subject.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

The study lenses will be worn in a bilateral and random fashion using a 5x5 crossover Williams design with 5 lens types and 5 periods. Two lens types will be fit at the first visit and three lens types will be fit at the second visit. Using a computer-generated randomization scheme provided by the study biostatistician, each subject will randomly be assigned to 1 of 10 unique sequences of the 5 lens types. Randomization will be stratified by site.

Permuted block randomization will be used to avoid bias in the assignment of subjects to treatment, and to enhance the validity of statistical comparisons across treatment groups. Each block will contain 10 different lens trial sequences.

The order of lens wear will be based on the randomization scheme assigned to the study site. The study site will follow the randomization scheme provided and will complete enrollment according to the randomization list and will not pre-select or assign subjects.

The following must have occurred prior to randomization:

- Informed consent has been obtained
- Subject met all the inclusion / exclusion criteria
- Subject history and baseline information has been collected

5.2. Masking

This is a double-masked study with the Subjects and Investigators being masked. Subjects will be unaware of the identity of the investigational product. Investigators and clinical site personnel involved in the data collection will be masked as to the identity of the investigational product.

Under normal circumstances, the mask should not be broken until all subjects have completed the study and the database is finalized. Otherwise, the mask should be broken only if specific emergency treatment/course of action would be dictated by knowing the treatment status of the subject. In such cases, the Investigator may, in an emergency, contact the medical monitor. In the event the mask is broken, the Sponsor must be informed as soon as possible. The date, time, and reason for the unmasking must be documented in the subject

record. The Investigator is also advised not to reveal the study treatment assignment to the clinical site or Sponsor personnel.

Subjects who have had their treatment assignment unmasked will be discontinued from the study. Subjects who are discontinued may be replaced.

5.3. Procedures for Maintaining and Breaking Randomization Codes

The test articles mask shall not be broken unless information concerning the lens type is necessary for the urgent medical treatment of a subject. The Sponsor must be notified before the mask is broken.

When dispensing test articles, the following steps should be followed to maintain randomization codes:

1. Investigator or designee (documented on the Delegation Log) will consult the lens fitting schedule/randomization scheme to obtain the test article assignment for that subject prior to dispensing
2. Investigator or designee will record the subject's number on the appropriate line of the randomization scheme
3. Investigator or designee will pull the appropriate test articles from the study supply. All test articles that are opened, whether dispensed (placed/fit on eye or dispensed outside the clinical site) or not, must be recorded on the Test Article Accountability Log in the "Dispensed" section

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Test Lenses				
	Test lens #1	Test lens #2	Test Lens #3	Test Lens #4	Control Lens
Name	JJVC Investigational Toric Multifocal Contact Lens for Presbyopia	JJVC Investigational Toric Multifocal Contact Lens for Presbyopia	JJVC Investigational Toric Multifocal Contact Lens for Presbyopia	JJVC Investigational Toric Multifocal Contact Lens for Presbyopia	JJVC Investigational Toric Multifocal Contact Lens for Presbyopia
Manufacturer	Johnson & Johnson® Vision Care, Inc.	Johnson & Johnson® Vision Care, Inc.	Johnson & Johnson® Vision Care, Inc.	Johnson & Johnson® Vision Care, Inc.	Johnson & Johnson® Vision Care, Inc.
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Lens Material	etafilcon A	etafilcon A	etafilcon A	etafilcon A	etafilcon A
Nominal Base Curve @ 22 °C	8.5 mm	8.5 mm	8.5 mm	8.5 mm	8.5 mm
Nominal Diameter @ 22 °C	14.5 mm	14.5 mm	14.5 mm	14.5 mm	14.5 mm
Nominal Distance Powers (D)	0.00	0.00	0.00	0.00	0.00
Nominal Cylinder Powers (D) and Axes	-1.00 D Axis 180°	-1.00 D Axis 180°	-1.00 D Axis 180°	-1.00 D Axis 180°	-1.00 D Axis 180°
Nominal ADD Powers (D)	MID	MID	MID	MID	MID
Water Content	58%	58%	58%	58%	58%
Peripheral Thickness	peripheral thickness +30 microns from nominal	peripheral thickness -16 microns from nominal	peripheral thickness -22 microns from nominal	peripheral thickness -28 microns from nominal	Nominal peripheral thickness

Oxygen Permeability (Dk)	28%	28%	28%	28%	28%
Modality in Current Study	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear
Replacement Frequency	Daily Disposable	Daily Disposable	Daily Disposable	Daily Disposable	Daily Disposable
Packaging Form (vial, blister, etc)	Blister	Blister	Blister	Blister	Blister

Given that the study is a crossover study and each subject will wear all 5 study lens types on both eyes each subject will use 10 lenses. Given that there are 80 subjects targeted to complete the study it is estimated that approximately 800 lenses will be used for the study.

6.2. Ancillary Supplies/Products

The following solutions will be used in this study: Eye-Cept® Rewetting drops maybe used to expedite the clearance of the fluorescein after biomicroscopy.

Table 2: Ancillary Supplies

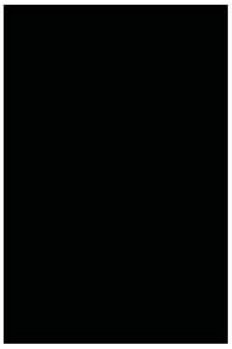
	Solution
Solution Name/Description	Eye-Cept® Rewetting Drops
Manufacturer	Optics Laboratory
Preservative	Non-preserved

6.3. Administration of Test Articles

The test articles will be dispensed to subjects meeting all eligibility requirements, including any dispensing requirements set forth in this clinical protocol. Subjects will be dispensed an adequate supply of test articles to complete the study. Lost or damaged test articles may be replaced at the discretion of the Investigator and/or the Sponsor.

6.4. Packaging and Labeling

The test articles will be packaged in blisters as the primary packaging. The test article will be over-labeled to mask the subject and Investigators to the identity of the lens. The test articles will be in plastic bags as the secondary packaging form. The sample study label is shown below:



6.5. Storage Conditions

Test articles will be maintained at ambient temperatures at the clinical site. Test articles must be kept under secure conditions.

6.6. Collection and Storage of Samples

When possible, any lens or test article associated with an Adverse Events and/or a Product Quality Complaint must be retained and stored in a glass vial with moderate solution pending directions from the sponsor for potential return back to JJVC.

6.7. Accountability of Test Articles

JJVC will provide the Investigator with sufficient quantities of test articles and supplies to complete the investigation. The Investigator is asked to retain all lens shipment documentation for the test article accountability records.

Test article must be kept in a locked storage cabinet, accessible only to those assigned by the Investigator for dispensing. The Investigator may delegate this activity to authorized study site personnel listed on the Site Delegation Log. All test articles must be accounted. This includes:

1. What was dispensed for the subject for trial fitting, to wear out of the office, or issued for the subject to replace appropriately between visits
2. What was returned to the Investigator unused
3. The number and reason for unplanned replacements.

The Investigator will collect all unused test articles from the subjects at the end of the subject's participation. Subject returned unused test articles must be separated from the clinical study inventory of un-dispensed test articles, and must be labeled with the subject number and date of return. Following final reconciliation of test articles by the monitor, the Investigator or monitor will package and return all unused test articles to JJVC.

If there is a discrepancy between the shipment documents and the contents, contact the study monitor immediately.

[redacted] Site Instructions for Test Article Receipt and Test Article Accountability for additional information.

7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 3: Time and Events

Visit Information	Visit 1 Screening, Baseline, Treatments 1 & 2	Visit 2 Baseline Treatments 3, 4, & 5
Time Point	Day 1	Day 7± 1
Estimated Visit Duration	2.0 hours	2.0 hours
Statement of Informed Consent	x	
Demographics	x	
Medical History/Concomitant Medications	x	x
Habitual Contact Lens	x	

Visit Information	Visit 1 Screening, Baseline, Treatments 1 & 2	Visit 2 Baseline Treatments 3, 4, & 5
Time Point	Day 1	Day 7± 1
Estimated Visit Duration	2.0 hours	2.0 hours
Information		
Contact Lens History	x	
Screening Inclusion/Exclusion Criteria	x	
Baseline Questionnaire	x	
Subject Reported Ocular Symptoms	x	x
Entrance Snellen Distance Visual Acuity	x	x
Habitual Lens Removal	x	x
Refraction	x	
Near Add Determination	x	
Biomicroscopy	x	x
Baseline Inclusion/Exclusion Criteria	x	
Continuance		x
Lens Selection	x	x
Right Lens Insertion	x	x
Timed Settling for Right Lens	x	x
Left Lens Insertion	x	x
Timed Settling for Left Lens	x	x
15 Minute Settling	x	x
Toric Fit Evaluation	x	x
Subjective Lens Fit Assessment	x	x
Post Fit Questionnaire	x	x
Study Lens Removal	x	x
Removal Questions	x	x
Subject Reported Ocular Symptoms	x	x
15 Minute Wash-Out	x	x
Exit Snellen Distance Visual Acuity	x	
Instructions	x	

Visit Information	Visit 1 Screening, Baseline, Treatments 1 & 2	Visit 2 Baseline Treatments 3, 4, & 5
Time Point	Day 1	Day 7± 1
Estimated Visit Duration	2.0 hours	2.0 hours
Final Evaluation		x

7.2. Detailed Study Procedures

VISIT 1

Subjects must report to the initial visit wearing their habitual contact lenses, in order to accurately assess baseline PRO performance. If the subject is not wearing their lenses they must be rescheduled.

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the consent form. **Note**: The subject must be provided a signed copy of this document.	
1.2	Demographics	Record the subject's date of birth, gender, race and ethnicity.	
1.3	Medical History and Concomitant Medications	Questions regarding the subjects' medical history and concomitant medications.	
1.4	Habitual Lenses	Questions regarding the subject's habitual lens type and parameters.	
1.5	Contact Lens History	Record the subject's correction type (ie, monovision, multifocal, sphere with readers, etc).	
1.6	Eligibility after Screening	All responses to Screening Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible.	

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.7	Baseline Questionnaire	The subject will evaluate the comfort characteristics, and handling characteristics of their habitual lenses using the PRO questions.	
1.8	Ocular Symptoms	If the subject reports ocular symptoms with their lenses they will be recorded in the Subject Reported Ocular Symptom Questionnaire	[redacted]
1.9	Entrance Visual Acuity	Distance Snellen visual acuity will be measured for each eye with the subject's habitual contact lenses in place. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
1.10	Lens Removal	Have the subject remove their habitual lenses and store in an approved storage solution	
1.11	Subjective Sphero-cylindrical Refraction	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. Record the refraction and distance visual acuity to the nearest letter (OD, OS, and OU).	[redacted]
1.12	Near Add Determination	The near reading addition will be determined using the binocular crossed cylinder technique at 40 cm	[redacted]
1.13	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments. If any of these slit lamp findings are Grade 3 or higher, the subject will be discontinued. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
1.14	Eligibility after Baseline	All responses to Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible.	

Visit 1: Treatment 1 Lens Fitting			
Step	Procedure	Details	[redacted]
1.15	Lens Selection	Assign the study lens based on the randomization scheme.	
1.16	Right Lens Insertion	Subjects will insert the right lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
1.17	Timed Settling for Right Lens	The investigator will start a stopwatch as soon as the right lens is inserted. Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal rotation to the nearest degree. At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
1.18	Left Lens Insertion	Subjects will insert the left lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
1.19	Timed Settling for Left Lens	The investigator will start a stopwatch as soon as the left lens is inserted. Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal rotation to	

		the nearest degree. At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
1.20	Lens Settling	Allow the study lenses to settle for a minimum of 15 minutes.	
1.21	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 40 degrees, or lens stability is worse than 10 degrees movement with blink. If toric fit is unacceptable, remove the lenses, perform biomicroscopy and proceed to final evaluation.* ***Note: If unacceptable fit save the lenses and store in saline in glass vials labeled appropriately.***	[redacted]
1.22	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement; • edge lift; • excessive movement in primary and up gaze; or • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up. *If either lens is deemed unacceptable, the subject will be discontinued from the study. Perform a slit-lamp evaluation and complete the Final Evaluation.*	[redacted]

		Note: If unacceptable fit save the lenses and store in saline in glass vials labeled appropriately.	
1.23	Post-Fit Questionnaire	The subject will respond to the PRO Post-Fit Questionnaire.	
1.24	Lens Removal	The Subject will remove the study lenses and store in saline in glass vials labeled appropriately.	
1.25	Removal Questions	The subject will respond to the removal questions.	
1.26	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
1.27	15 Minute Wash-out	Subjects will complete a wash-out period for at least 15 minutes. Subjects can wear their glasses during this period.	

Visit 1: Treatment 2 Lens Fitting			
Step	Procedure	Details	[redacted]
1.28	Lens Selection	Assign the study lens based on the randomization scheme.	
1.29	Right Lens Insertion	Subjects will insert the right lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
1.30	Timed Settling for Right Lens	The investigator will start a stopwatch as soon as the right lens is inserted. Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal rotation to the nearest degree. At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
1.31	Left Lens Insertion	Subjects will insert the left lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
1.32	Timed Settling for Left Lens	The investigator will start a stopwatch as soon as the left lens is inserted. Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal rotation to	

		the nearest degree. At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
1.33	Lens Settling	Allow the study lenses to settle for a minimum of 15 minutes.	
1.34	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 40 degrees, or lens stability is worse than 10 degrees movement with blink. If toric fit is unacceptable, remove the lenses, perform biomicroscopy and proceed to final evaluation.* ***Note: If unacceptable fit save the lenses and store in saline in glass vials labeled appropriately.***	[redacted]
1.35	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement; • edge lift; • excessive movement in primary and up gaze; or • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up. *If either lens is deemed unacceptable, the subject will be discontinued from the study. Perform a slit-lamp evaluation and complete the Final Evaluation.*	[redacted]

		Note: If unacceptable fit save the lenses and store in saline in glass vials labeled appropriately.	
1.36	Post-Fit Questionnaire	The subject will respond to the PRO Post-Fit Questionnaire	
1.37	Lens Removal	Subjects will remove the study lenses and store in saline in glass vials labeled appropriately.	
1.38	Removal Questions	The subject will respond to the Removal Questions.	
1.39	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
1.40	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments. If any of these slit lamp findings are Grade 3 or higher, the subject will be discontinued. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
1.41	Exit VA	Record subjects' distance visual acuity, OD, OS and OU to the nearest letter with their habitual correction in place.	[redacted]
1.42	Instructions	Schedule the subject to return in 7±1 Day for Visit 2	

VISIT 2

Visit 2: Baseline 1			
Step	Procedure	Details	[redacted]
2.1.	Adverse Events and Concomitant Medications Review	Review the subject's concomitant medications and record any changes from the previous study visit. Record any adverse events or medical history changes from the previous study visit.	
2.2.	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
2.3.	Visual Acuity	Distance Snellen visual acuity will be measured for each eye with the subject's habitual correction in place. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
2.4.	Lens Removal (if applicable)	Have the subject remove their habitual lenses and store in an approved storage solution.	
2.5.	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments. If any of these slit lamp findings are Grade 3 or higher, the subject will be discontinued. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
2.6.	Continuance	Determine whether the subject is eligible to continue in the study based on the examination findings.	

Visit 2: Treatment 3 Lens Fitting			
Step	Procedure	Details	[redacted]
2.7.	Lens Selection	Assign the study lens based on the randomization scheme.	
2.8.	Right Lens Insertion	Subjects will insert the right lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
2.9.	Timed Settling for Right Lens	The investigator will start a stopwatch as soon as the right lens is inserted. Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal rotation to the nearest degree. At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
2.10	Left Lens Insertion	Subjects will insert the left lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
2.11	Timed Settling for Left Lens	The investigator will start a stopwatch as soon as the left lens is inserted. Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal rotation to the nearest degree.	

		At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
2.12	Lens Settling	Allow the study lenses to settle for a minimum of 15 minutes.	
2.13	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 40 degrees, or lens stability is worse than 10 degrees movement with blink. If toric fit is unacceptable, remove the lenses, perform biomicroscopy and proceed to final evaluation.* ***Note: If unacceptable fit save the lenses and store in saline in glass vials labeled appropriately.***	[redacted]
2.14	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement; • edge lift; • excessive movement in primary and up gaze; or • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up. *If either lens is deemed unacceptable, the subject will be discontinued from the study. Perform a slit-lamp evaluation and complete the Final Evaluation.*	[redacted]

		Note: If unacceptable fit save the lenses and store in saline in glass vials labeled appropriately.	
2.15	Post-Fit Questionnaire	The subject will respond to the PRO Post-Fit Questionnaire	
2.16	Lens Removal	Subjects will remove the study lenses and store in saline in glass vials labeled appropriately.	
2.17	Removal Questions	The subject will respond to the Removal Questions.	
2.18	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
2.19	15 Minute Wash-out	Subjects will complete a wash-out period for at least 15 minutes. Subjects can wear their glasses during this period.	

Visit 2: Treatment 4 Lens Fitting			
Step	Procedure	Details	[redacted]
2.20	Lens Selection	Assign the study lens based on the randomization scheme.	
2.21	Right Lens Insertion	Subjects will insert the right lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
2.22	Timed Settling for Right Lens	The investigator will start a stopwatch as soon as the right lens is inserted. Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal rotation to the nearest degree. At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
2.23	Left Lens Insertion	Subjects will insert the left lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
2.24	Timed Settling for Left Lens	The investigator will start a stopwatch as soon as the left lens is inserted. Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal rotation to the nearest degree.	

		At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
2.25	Lens Settling	Allow the study lenses to settle for a minimum of 15 minutes.	
2.26	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 40 degrees, or lens stability is worse than 10 degrees movement with blink. If toric fit is unacceptable, remove the lenses, perform biomicroscopy and proceed to final evaluation.* ***Note: If unacceptable fit save the lenses and store in saline in glass vials labeled appropriately.***	[redacted]
2.27	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement; • edge lift; • excessive movement in primary and up gaze; or • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up. *If either lens is deemed unacceptable, the subject will be discontinued from the study. Perform a slit-lamp evaluation and complete the Final Evaluation.* ***Note: If unacceptable fit save the lenses and store in saline in glass vials labeled appropriately.***	[redacted]

2.28	Post-Fit Questionnaire	The subject will respond to the PRO Post-Fit Questionnaire	
2.29	Lens Removal	Subjects will remove the study lenses and store in saline in glass vials labeled appropriately.	
2.30	Removal Questions	The subject will respond to the Removal Questions.	
2.31	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
2.32	15 Minute Wash-out	Subjects will complete a wash-out period for at least 15 minutes. Subjects can wear their glasses during this period.	

Visit 2: Treatment 5 Lens Fitting			
Step	Procedure	Details	[redacted]
2.33	Lens Selection	Assign the study lens based on the randomization scheme.	
2.34	Right Lens Insertion	Subjects will insert the right lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
2.35	Timed Settling for Right Lens	The investigator will start a stopwatch as soon as the right lens is inserted. Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal rotation to the nearest degree. At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
2.36	Left Lens Insertion	Subjects will insert the left lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
2.37	Timed Settling for Left Lens	The investigator will start a stopwatch as soon as the left lens is inserted. Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line.	

		Record base nasal or base temporal rotation to the nearest degree. At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
2.38	Lens Settling	Allow the study lenses to settle for a minimum of 15 minutes.	
2.39	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable *Toric lens fit will be unacceptable if lenses rotated more than 40 degrees, or lens stability is worse than 10 degrees movement with blink. If toric fit is unacceptable, remove the lenses, perform biomicroscopy and proceed to final evaluation.* ***Note: If unacceptable fit save the lenses and store in saline in glass vials labeled appropriately.***	[redacted]
2.40	Subjective Lens Fit Assessment	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement; • edge lift; • excessive movement in primary and up gaze; or • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up. *If either lens is deemed unacceptable, the subject will be discontinued from the study. Perform a slit-lamp evaluation and complete*	[redacted]

		the Final Evaluation. ***Note: If unacceptable fit save the lenses and store in saline in glass vials labeled appropriately.***	
2.41	Post-Fit Questionnaire	The subject will respond to the PRO Post-Fit Questionnaire	
2.42	Lens Removal	Subjects will remove the study lenses and store in saline in glass vials labeled appropriately.	
2.43	Removal Questions	The subject will respond to the Removal Questions.	
2.44	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
2.45	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments. If any of these slit lamp findings are Grade 3 or higher, the subject will be discontinued. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]

FINAL EVALUATION

The final evaluation will ordinarily take place immediately following the last scheduled follow-up visit per the study protocol. It may also take place at any point the subject discontinues the study or is terminated from the study.
If the subject is a screen-failure and a refraction and/or biomicroscopy procedure has just been performed, you may intentionally blank out these forms at the Final Evaluation in EDC.

Final Evaluation			
Step	Procedure	Details	[redacted]
F.1	Subjective Sphero-cylindrical Refraction and Distance Exit Visual Acuity	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. Record the refraction and distance visual acuity to the nearest letter.	[redacted]
F.2	Subject Disposition	Indicate if the subject completed the study successfully. If subject discontinued from the study indicate the reason.	

7.3 Unscheduled Visits

If, during the investigation, a subject requires an unscheduled visit to the clinical site, the following information will be collected at a minimum:

- Chief complaint prompting the visit. If the reason is an adverse event, the applicable eCRF for the adverse event must be completed and subject record completed as appropriate
- Date and time of the visit and all procedures completed at the unscheduled visit
- Review of adverse event and concomitant medications
- Documentation of any test article dispensed or collected from the subject, if applicable
- Slit lamp findings (using the Slit Lamp Classification Scale)

If the Investigator withdraws a subject from the study, the final study visit case report forms must be completed indicating the reason(s) why the subject was withdrawn. The subject record must be completed documenting the date and primary reason for withdrawal and the study CRA notified.

Any ocular and non-ocular Adverse Events that are ongoing at the time of the study visit will be followed by the Investigator, within licensure, until they have resolved, returned to pre-treatment status, stabilized, or been satisfactorily explained. If further treatment ie, beyond licensure is required, the subject will be referred to the appropriate health care provider.

The following information will be collected during an unscheduled visit.

Step	Procedure	Details	[redacted]
U.1	Chief Complaints	Record the subject's chief complaints for reasons for the unscheduled visit	
U.2	Change of Medical History and Concomitant Medications	Questions regarding the change of subjects' medical history and concomitant medications.	
U.3	Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire.	[redacted]
U.4	Entrance VA	Record the entrance distance visual acuity (OD, OS and OU) to the nearest letter.	[redacted]
U.5	Subjective Sphero-cylindrical Refraction	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. Record the refraction and distance visual acuity to the nearest letter.	[redacted]
U.6	Biomicroscopy	FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments. If any of these slit lamp findings are Grade 3 or higher, the subject will be discontinued. If discontinued a final examination must be completed. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled.	[redacted]
U.7	Exit Visual Acuity	Record the subject's exit distance visual acuity (OD, OS and OU) to the nearest letter.	[redacted]

7.4 Laboratory Procedures

Not Applicable.

8. SUBJECTS COMPLETION/WITHDRAWAL

8.1. Completion Criteria

Subjects are considered to have completed the study if they:

- provided informed consent;
- they are eligible;
- have not withdrawn/discontinued for any reason described in Section 8.2;
- Complete all study visits

8.2. Withdrawal/Discontinuation from the Study

A subject will be withdrawn from the study for any of the following reasons:

- Subject death during the study period
- Subject withdrawal of consent
- Subject not compliant to protocol
- Subject lost to follow-up
- Subject no longer meets eligibility criteria (eg, the subject becomes pregnant)
- Subject develops significant or serious adverse events causing discontinuation of study lens wear
- Subjects who have experienced a Corneal infiltrative Event (CIE)
- Investigator's clinical judgment regarding the subject safety reasons (that it is in the best interest of the subject to stop treatment)
- Subject not compliant with study lens wear schedule
- Subject not successfully dispensed due to lack of efficacy and safety including poor vision, poor comfort or unacceptable fit

For discontinued subjects, the Investigator will:

- Complete the current visit (scheduled or unscheduled)
- Complete the Final Evaluation, indicating the reason that the subject was discontinued from the study
- Record the spherocylindrical refraction with best corrected distance visual acuity
- Collect used test article(s) (worn or brought to the visit) from the subject and discard them, unless otherwise stated in Section 7.2
- Collect all unused test article(s) from the subject

An additional subject may be enrolled if a subject discontinues from the study prematurely.

In cases where a subject is lost to follow-up, every possible effort must be made to contact the subject and determine the reason for discontinuation/withdrawal. The measures taken to follow up must be documented including two written attempts and a certified letter (or equivalent) as the final attempt.

9. PRE-STUDY AND CONCOMITANT INTERVENTION/MEDICATION

Concomitant medications will be documented during screening and updated during the study. Disallowed medications for this study include: Any ocular medications with the exception of rewetting drops.
Concomitant therapies that are disallowed include: Any therapies that may contraindicate lens wear.

10. DEVIATIONS FROM THE PROTOCOL

Investigator will notify study sponsor upon identification of a protocol deviation. Major protocol deviations must be reported to the sponsor within 24 hours after discovery of the protocol deviation. The Investigator will report deviations per IRB/IEC requirements. All deviations will be tracked and corrective actions implemented as appropriate.

If it becomes necessary for the Investigator to implement a deviation in order to eliminate an immediate hazard to the trial subject, the Investigator may implement the deviation immediately without notification to the sponsor. Within 24 hours after the implemented deviation, the Investigator must notify and provide the rationale to the Sponsor and, as required, the IEC/IRB.

11. STUDY TERMINATION

If more than 2 subjects in the investigational soft contact lens group develop serious expected (eg, definite or probable MK) or unexpected device related adverse events, the study will be suspended. Upon review and consultation with IRB, DMC, and JJVC safety review committee, the study may be terminated.

The occurrence of one or more Unanticipated Serious Adverse Device Effect (USADE), or any SAE where the relationship to study agent cannot be ruled out, may result in stopping further dispensing of test article. In the event of a USADE or SAE, the Sponsor may unmask the treatment regimen for the subject(s) and will discuss this with the Investigator before any further subjects are enrolled.

The Sponsor will determine when a study will be stopped. The Principal Investigator always has the discretion to initiate stopping the study based on patient safety or if information indicates the study's results are compromised.

JJVC reserves the right to terminate the study at any time for any reason. Additionally, the IEC/IRB reserves the right to terminate the study if an unreasonable risk is determined. The study can be terminated by the Principal Investigator at the individual clinical site due to specific clinical observations, if in their opinion, after a discussion with JJVC, it is determined that it would be unwise to continue at the clinical site.

JJVC (and the IEC/IRB and DMC, if applicable) will evaluate all adverse events. If it is determined that an adverse event presents an unreasonable risk, the investigation, or that part of the investigation presenting the risk, will be terminated, as soon as possible.

Should the study be terminated (either prematurely or as scheduled), the Investigator will notify the IEC/IRB and Regulatory Authority as required by local regulatory requirements.

12. PROCEDURE FOR HANDLING PRODUCT QUALITY COMPLAINTS

A Product Quality Complaint (PQC) refers to any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of test articles after they have been released for clinical trial use.

Potential complaints may come from a variety of sources including but not limited to subjects, clinical research associates (CRA), clinical operations managers (COM), medical monitors, and site personnel, etc. The following are not considered product quality complaints:

- Subject satisfaction inquiries reported via "Subjective Questionnaires" and "Patient Reported Outcomes (PRO)".
- Clinical test articles that are stored improperly or damaged after receipt at the investigational site.
- Lens replacements that occur due to drops/fall-outs.
- Damage deemed by clinicians or clinical staff to be caused by handling by the user, and not indicative of a quality deficiency (ie, tears, rips, etc), only in situations where there is no deficiency alleged by the subject.

Within 24 hours of site personnel becoming aware that a PQC has occurred, the PQC must be recorded in the EDC system, which will trigger an automatic email notification to the appropriate COM/CRA and Clinical QA representative. In cases where the EDC system in use is not configured to send automatic notifications or when an EDC system is not used, the COM/CRA is responsible for notifying Clinical QA upon discovery that a PQC has occurred.

Upon receipt of the EDC notification, the COM/CRA will contact the study site to collect additional information which will include:

- Date the complaint was received/recorded in the EDC System (Date of Sponsor Awareness)
- Who received the complaint
- Study number
- Clinical site information (contact name, site ID, telephone number)
- Lot number(s)
- Unique Subject Identifier(s)
- Indication of who first observed complaint (site personnel or subject)
- OD/OS indication, along with whether or not the lens was inserted
- Any related AE number if applicable

- Detailed complaint description (scheduled/unscheduled visit, wear time, symptoms, resolution of symptoms, etc)
- Eye Care Provider objective (slit lamp) findings if applicable
- Confirmation of product availability for return (and tracking information, if available), or rationale if product is not available for return ([redacted] for test article return instructions)

Once a complaint is received, it will be assessed by the COM, CRA, or trained site personnel to determine if it is an Adverse Event/Serious Adverse Event (AE/SAE). If the complaint results in an AE/SAE, the COM/CRA, or trained site personnel will follow Section 13 of this protocol. If the AE/SAE was potentially the result of a product quality related deficiency, these procedures also applies and will be executed in parallel.

In some cases, a PQC form may be generated in EDC by the site in error. In this event, the PQC forms will be marked "Intentionally Left Blank" or "ILB". Justification for ILB must be documented.

13. ADVERSE EVENTS

13.1. Definitions and Classifications

Adverse Event (AE) – An AE is any untoward (unwanted) medical occurrence in a patient or clinical investigation subject administered a test article, study treatment or study procedure whether or not caused by the test article, study treatment or procedure. An AE can therefore be any unfavorable or unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of the test article, study treatment, or study procedure whether or not related to the test article, study treatment, or study procedure.

An AE includes any condition (including a pre-existing condition) that:

1. Was not present prior to the study , but appeared or reappeared following initiation of the study
2. Was present prior to the study, but worsened during the study. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states
3. Pregnancy must be documented as an adverse event and must be reported to the clinical monitor and to the Sponsor immediately upon learning of the event

Serious Adverse Event (SAE) – An SAE is any untoward medical occurrence that:

- Results in death
- Is life threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity (eg, a sight threatening event, a significant persistent or permanent change, impairment, damage, or disruption to the subject's body)
- Is a congenital anomaly/birth defect, or

- Requires intervention to prevent permanent damage (the use of the test article resulting in a condition which requires medical or surgical intervention to preclude permanent impairment of the body structure or a body function). Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in the above definition.

Diagnoses and conditions that are considered Ocular Serious Adverse Events include, but not limited to:

- Microbial Keratitis (MK)
- Iritis (including cells in the anterior chamber)
- Permanent decrease in best spectacle corrected visual acuity equivalent to 2 acuity lines or greater
- Central Corneal Opacity
- Central Corneal Neovascularization
- Uveitis
- Endophthalmitis
- Hypopyon
- Hyphemia
- Penetration of Bowman's Membrane
- Persistent Epithelial Defect
- Limbal cell Damage leading to Conjunctivalization

Significant Adverse Events – Those events that are usually symptomatic and warrant discontinuation (temporary or permanent) of the test article (excluding Serious Adverse Events).

Diagnoses and conditions that are considered Ocular Significant Adverse Events include, but not limited to the following:

- Contact Lens Induced Peripheral Ulcer (CLPU)
- Significant Infiltrative Events (SIE)
- Superior Epithelial Arcuate Lesions (SEALs)
- Any Temporary Loss of > 2 Lines of BSCVA
- Other Grade 3 or higher corneal findings, such as abrasions or edema
- Non-contact lens related corneal events - eg, Epidemic Keratoconjunctivitis (EKC)
- Asymptomatic Corneal Scar
- Any corneal event which necessitates temporary lens discontinuation > 2 weeks

Non-Significant Adverse Events – Those conditions that are usually asymptomatic and usually do not warrant discontinuation (temporary or permanent) of the test article. However, the Investigator may choose to treat as a precautionary measure.

Diagnoses and conditions that are considered Ocular Non-Significant Adverse Events include, but not limited to the following:

- Non-significant Infiltrative Event (NSIE)
- Contact Lens Papillary Conjunctivitis (CLPC)
- Superficial Punctate Keratitis (SPK)
- Conjunctivitis: Bacterial, Viral, Allergic
- Blepharitis
- Meibomianitis
- Contact Dermatitis
- Localized Allergic Reactions
- Any corneal event not explicitly defined as serious or significant adverse event, which necessitates temporary lens discontinuation < 2 weeks

Adverse Device Effect (ADE) – A sub-set of AEs, and include only those adverse events that are cause by or related to the investigational device.

Unanticipated Adverse Device Effect (UADE) – Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, the test article, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, Investigator's Brochure or protocol, or any other unanticipated serious problem associated with the test article that relates to the rights, safety and welfare of subjects.

13.2. Assessing Adverse Events

In conjunction with the medical monitor, the Investigator will evaluate adverse events to ensure the events are categorized correctly. Elements of categorization will include:

- Seriousness/Classifications (see definition in Section 13.1)
- Causality or Relatedness – ie, the relationship between the test article, study treatment or study procedures and the adverse event (not related; doubtful; possible; probable; very likely - see definition in Section 13.2.1)
- Adverse Event Severity – Adverse event severity is used to assess the degree of intensity of the adverse event (mild; moderate; severe for all events - see definition in Section 13.2.2).
- Outcome – Not Recovered or Not Resolved; Recovering or Resolving; Recovered or Resolved with Sequelae; Recovered or Resolved; Death Related to Adverse Event; Unknown
- Actions Taken – None; temporarily discontinued; permanently discontinued; other action taken

13.2.1 Causality Assessment

Causality Assessment – A determination of the relationship between an adverse event and the test article, study treatment, or study procedure. The test article, study treatment or study procedure relationship for each adverse event shall be determined by the Investigator using these explanations:

- Not Related- An adverse event that is not related to the use of the test article, study treatment or study procedures.

- Doubtful – An adverse event for which an alternative explanation is more likely, eg, concomitant treatment, concomitant disease(s), or the relationship of time suggests that a causal relationship is unlikely.
- Possible – An adverse event that might be due to the use of the test article, or to the study treatment or study procedures. An alternative explanation, eg, concomitant treatment, concomitant disease(s), is inconclusive. The relationship in time is reasonable. Therefore, the causal relationship cannot be excluded.
- Probable – An adverse event that might be due to the use of the test article. The relationship in time is suggestive (eg, confirmed by de-challenge). An alternative explanation is less likely, eg, concomitant treatment or concomitant disease(s).
- Very Likely – An adverse event that is listed as a possible adverse effect (device) or adverse reaction (drug) and cannot be reasonably explained by an alternative explanation, eg, concomitant treatment of concomitant disease(s). The relationship in time is very suggestive, eg, it is confirmed by de-challenge and re-challenge.

13.2.2 Severity Assessment

Severity Assessment – A qualitative assessment of the degree of intensity of an adverse event as determined by the Investigator or reported to him/her by the subject. The assessment of severity is made irrespective of test article, study treatment or study procedure relationship or seriousness of the event and should be evaluated according to the following scale:

- Mild – Event is noticeable to the subject, but is easily tolerated and does not interfere with the subject's daily activities
- Moderate – Event is bothersome, possible requiring additional therapy, and may interfere with the subject's daily activities
- Severe – Event is intolerable, necessitates additional therapy or alteration of therapy and interferes with the subject's daily activities

13.3. Documentation and Follow-Up of Adverse Events

The recording and documenting of adverse events (ocular and non-ocular) begins when the subjects are exposed to the test article, study treatment or study procedure. Adverse events reported before the use of test article, start of study treatment, or study procedures will be recorded as medical history. However, if the condition deteriorates at any time during the study it will be recorded and reported as an AE. Untoward medical events reported after the subject's exit from the study will be recorded as adverse events at the discretion of the Investigator.

Upon finding an adverse event, the Principal Investigator will document the condition in the subject record and in the eCRFs. He/she will complete the Adverse Event /eCRF.

Complete descriptions of all adverse events must be available in the subject record. All Adverse Events including local and systemic reactions not meeting the criteria for "serious adverse events" shall be captured on the appropriate case report form or electronic data system. All adverse events occurring while the subject is enrolled in the study must be documented appropriately regardless of relationship.

It is the Investigator's responsibility to maintain documentation of each reported adverse event. All adverse events will be followed in accordance with applicable licensing requirements. Such documentation will include the following:

- Adverse event (diagnosis not symptom)
- Drawings or photographs (where appropriate) that detail the finding (eg, size, location, and depth, etc)
- Date the clinical site was notified
- Date and time of onset
- Date and time of resolution
- Adverse event classification, severity, and relationship to test articles, as applicable
- Treatment regimen instituted, including concomitant medications prescribed, in accordance with applicable licensing requirements
- Any referral to another health care provider if needed
- Outcome, ocular damage (if any)
- Likely etiology
- Best corrected visual acuity at the discovery of the event and upon conclusion of the event

In addition, if an infiltrate(s) is present, he/she will complete the Corneal Infiltrate Assessment /eCRF. Where necessary, a culture of the corneal lesion will be collected to determine if the infection is microbial in nature. If cultures are collected, the date of culture collection and laboratory utilized will be recorded.

Changes in the severity of an AE shall be documented to allow an assessment of the duration of the event at each level of intensity to be performed. Adverse events characterized as intermittent require documentation of the onset and duration of each episode. Changes in the assessment of relationship to the Test Article shall also be clearly documented.

Subjects who present with an adverse event shall be followed by the Investigator, within licensure, until all signs and symptoms have returned to pre-treatment status, stabilized, or been satisfactorily resolved. If further treatment beyond licensure is required, the patient will be referred to the appropriate health care provider. The Investigator will use his/her clinical judgment as to whether or not a subject reporting with an adverse event will continue in the study. If a subject is discontinued from the study, it will be the responsibility of the Investigator to record the reason for discontinuation. The Investigator will also document the adverse event appropriately and complete the Adverse Event /eCRF. Any subjects with ongoing adverse events related to the test article, study treatment or study procedures, as of the final study visit date should be followed to resolution of the adverse event or until referral to an appropriate health care provider, as recommended by the Investigator.

13.4. Reporting Adverse Events

The Investigator will notify the Sponsor of an adverse event by e-mail, facsimile, or telephone as soon as possible and no later than 24 hours from discovery for any serious /significant adverse events, and 2 days from discovery for any non-significant adverse event. In addition, a written report will be submitted by the Principal Investigator to the IEC/IRB

according to their requirements (Section 13.4.2). The report will comment whether or not the adverse event was considered to be related to the test article, study treatment or study procedures.

13.4.1 Reporting Adverse Events to Sponsor

Serious/Significant Adverse Events

The Investigator will inform the sponsor of all serious/significant adverse events occurring during the study period as soon as possible by e-mail, fax, or telephone, but no later than 24 hours following discovery of the event. The Investigator is obligated to pursue and obtain information requested by the Sponsor in addition to that information reported on the eCRF. All subjects experiencing a serious/significant adverse event must be followed up and all outcomes must be reported.

When medically necessary, the Investigator may break the randomization code to determine the identity of the treatment that the subject received. The Sponsor and study monitor should be notified prior to unmasking the test articles.

In the event of a serious/significant adverse event, the Investigator must:

- Notify the Sponsor immediately
- Obtain and maintain in the subject's records all pertinent medical information and medical judgment for colleagues who assisted in the treatment and follow-up of the subject
- Provide the Sponsor with a complete case history which includes a statement as to whether the event was or was not related to the use of the test article
- Notify the IEC/IRB as required by the IEC/IRB reporting procedure according to national regulations

Unanticipated (Serious) Adverse Device Effect (UADE)

In the event of an Unanticipated (Serious) Adverse Device Effect (UADE), the Investigator will submit a report of the UADE to the Sponsor and IEC/IRB as soon as possible, but no later than 24 hours after the Investigator first learns of the effect. This report is in addition to the immediate notification mentioned above.

The Sponsor must conduct an evaluation of the UADE and must report the results of the evaluation to FDA, the IEC/IRB and participating Investigators within 10 working days after the Sponsor first receives notification of the effect.

Non-Serious Adverse Events

All non-serious adverse events, including non-serious adverse device effects, will be reported to the sponsor by the Investigator no later than 2 days from discovery.

13.4.2 Reporting Adverse Events to the Responsible IEC/IRB and Health Authorities

Adverse events that meet the IEC/IRB requirements for reporting must be reported within the IEC/IRB's written guidelines. Each clinical site will refer to and follow any guidelines set

forth by their Approving IEC/IRB. Each clinical site will refer to and follow any guidelines set forth by their local governing Health Authorities.

The Sponsor will report applicable Adverse Events to the local health authorities according the written guidelines, including reporting timelines.

13.5. Event of Special Interest

Not Applicable.

13.6. Reporting of Pregnancy

Subjects reporting pregnancy (by self-report) during the course of the study will be discontinued after the event is recorded as an Adverse Event. Once discontinued, pregnant participants and their fetuses will not be monitored for study related purposes. At the Investigator's discretion, the study participant may be followed by the Investigator through delivery. However, this data will not be collected as part of the clinical study database. Pregnant participants are not discontinued from contact lens or solution related studies for safety concerns, but due to general concerns relating to pregnancy and contact lens use. Specifically, pregnant women are discontinued due to fluctuations in refractive error and/or visual acuity that occur secondary to systemic hormonal changes, and not due to unforeseen health risks to the mother or fetus.

14. STATISTICAL METHODS

14.1. General Considerations

All data summaries and statistical analyses will be performed using the SAS software Version 9.4 (SAS Institute, Cary, NC). Throughout the analysis of data, the results for each subject/eye will be used when available for summarization and statistical analysis. Unscheduled visits will be summarized separately and will be excluded from the statistical analysis.

Summary tables (Descriptive statistics and/or frequency tables) will be provided for all baseline variables, efficacy variables and safety variables as appropriate. Continuous variables will be summarized with descriptive statistics (n, mean, standard deviation [SD], median, minimum and maximum). Frequency count and percentage of subjects or eyes within each category will be provided for categorical data.

Summaries will be presented by study lens type and will be performed separately by completion status. All analyses will be conducted on per-protocol population (see Section 14.3).

14.2. Sample Size Justification

232 cohort subjects from [redacted] were used as historical input for the sample size calculation. The lenses used in the above single arm studies had the same optical design as the lenses used in this trial. The standard deviation of CLUE handling from visit 2 and 3 was the input for calculating the sample size.

The true difference between the Test lens and the Control lens was assumed to be 0 and -1 points to make 2 different scenarios. It is reasonable to further assume the handling scores from different lenses are correlated since the only difference in the lenses is the thickness profile (correlation is assumed to be 0.6 and 0.7).

Below is the summary of sample size required to test the primary hypotheses at alpha = 0.05 and power at least 0.8

Mean Diff	Correlation	Actual Power	Sample Size
0	0.6	0.802	**116**
0	0.7	0.801	**87**
-1	0.6	0.801	**180**
-1	0.7	0.800	**135**

14.3. Analysis Populations

Safety Population:
All subjects who were administered any test article excluding subjects who drop out prior to administering any test article. At least one observation should be recorded.

Per-Protocol Population:
All subjects who have successfully completed all visits and did not substantially deviate from the protocol as determined by the trial cohort review committee prior to database hard lock (Per-Protocol Population). Justification of excluding subjects with protocol deviations in the per-protocol population set will be documented in a memo to file.

Intent-to-Treat (ITT) Population:
All randomized subjects regardless of actual treatment and subsequent withdrawal from study or deviation from protocol. At least one observation should be recorded.

14.4. Level of Statistical Significance

All planned analysis for this study will be conducted with an overall type I error rate of 5%.

14.5. Primary Analysis

Primary efficacy analysis:
The CLUE handling score will be analyzed using a linear mixed model. The model will include the experimental design factors: sequence of lens wear, lens wearing period and lens type as fixed effects. Site and subject nested in site will be included as random effects. Age and gender will be included as fixed covariates when appropriate. The covariance between residual errors from the same subject across lens wearing periods will be selected based on the finite-sample corrected Akaike's Information Criterion (Keselman et al. 1998[2]). Covariance structures considered may include: Homogenous compound symmetry (CS) and Unstructured covariance structure (UN). The structure that returns the lowest Akaike Information Criteria Corrected (AICC) will be selected as the structure that best fit the data.

Comparisons between each Test lens and Control lens will be carried out using 95% confidence intervals constructed of least-square means (LSM) differences (Test minus Control) from the linear mixed models. Non-inferiority will be concluded if the lower confidence limit is greater than -5 points.

In all models, the Kenward and Roger method (Kenward and Roger, 1997) will be used for the calculation of the denominator of degrees of freedom.

14.6. Secondary Analysis

Secondary efficacy analysis:
The secondary analysis will be conducted using the same method as the primary analysis.

14.7. Other Exploratory Analyses

Not Applicable.

14.8. Interim Analysis

Not Applicable.

14.9. Procedure for Handling Missing Data and Drop-Outs

Missing or spurious values will not be imputed. The count of missing values will be included in the summary tables and listings.

Subject dropout is expected to be one of the main reasons of missing data in this clinical trial. Past clinical trials don't provide the evidence that subject dropout is systematic or not-at-random. To evaluate the impact of missing data, sensitivity analysis will be conducted using multiple imputation methods if the proportion of subject dropout is greater than the 15%. The SAS/STAT procedures PROC MI and PROC MIANALYZE will be utilized with a parametric regression method used to make at least 5 imputations.

14.10. Procedure for Reporting Deviations from Statistical Plan

The analysis will be conducted according to that specified in above sections. There are no known reasons for which it is planned to deviate from these analysis methods. If for any reason a change is made, the change will be documented in the study report along with a justification for the change.

15. DATA HANDLING AND RECORD KEEPING/ARCHIVING

15.1. Electronic Case Report Form/Data Collection

The data for this study will be captured on electronic case report forms (eCRFs) using Bioclinica Express version 5.5 EDC system). An authorized data originator will enter study data into the eCRFs using the EDC system. Data collected on equipment that is not captured in EDC will be formatted to the specification of the JJVC database manager and sent to JJVC for analysis.

The clinical data will be recorded on dedicated eCRFs specifically designed to match the study procedures for each visit. Once completed, the eCRFs will be reviewed for accuracy and completeness and signed by the Investigator. The sponsor or sponsor's representatives will be authorized to gain access to the subject recordation for the purposes of monitoring and auditing the study.

Edit checks, electronic queries, and audit trails are built into the system to ensure accurate and complete data collection. Data will be transmitted from the clinical site to a secure central database as forms are completed or updated, ensuring information accuracy, security, and confidentiality. After the final database lock, the Investigator will be provided with Individual Patient Profiles (IPP) including the full audit trail on electronic media in PDF format for all of the study data. The IPP must be retained in the study files as a certified copy of the source data for the study.

The content and structure of the eCRFs are compliant with ISO14155:2011.

15.2. Subject Record

At a minimum, subject record should be available for the following:

- subject identification
- eligibility
- study identification
- study discussion
- provision of and date of informed consent
- visit dates
- results of safety and efficacy parameters as required by the protocol
- a record of all adverse events
- follow-up of adverse events
- medical history and concomitant medication
- test article receipt/dispensing/return records
- date of study completion
- reason for early discontinuation of test article or withdrawal from the study, if applicable

The subject record is the eCRF or an external record. The author of an entry in the subject record must be identifiable. The first point of entry is considered to be the source record.

Adverse event notes must be reviewed and initialed by the Investigator.

16. DATA MANAGEMENT

16.1. Access to Source Data/Document

The Investigator/Institution will permit trial-related monitoring, audits, IEC/IRB review and regulatory inspection(s) by providing direct access to source data/documents. Should the clinical site be contacted for an audit by an IEC/IRB or regulatory authority, JJVC must be contacted and notified in writing within 24 hours.

16.2. Confidentiality of Information

Information concerning the investigational product and patent application processes, scientific data or other pertinent information is confidential and remains the property of JJVC. The Investigator may use this information for the purposes of the study only. It is understood by the Investigator that JJVC will use information developed in this clinical study in connection with the development of the investigational product and therefore may disclose it as required to other clinical investigators and to regulatory agencies. In order to allow the use of the information derived from this clinical study, the Investigator understands that he/she has an obligation to provide complete test results and all data developed during this study to the Sponsor.

16.3. Data Quality Assurance

Steps will be taken to ensure the accuracy and reliability of data, include the selection of qualified investigators and appropriate clinical sites and review of protocol procedures with the Principal Investigator. The Principal Investigator, in turn, must ensure that all Sub-Investigators and clinical site personnel are familiar with the protocol and all study-specific procedures and have appropriate knowledge of the study article.

Training on case report form completion will be provided to clinical site personnel before the start of the study. The Sponsor will review case report forms for accuracy and completeness remotely during the conduct of the study, during monitoring visits, and after transmission to data management. Any data discrepancies will be resolved with the Investigator or designee, as appropriate.

Quality Assurance representatives from JJVC may visit clinical sites to review data produced during the study and to access compliance with applicable regulations pertaining to the conduct of clinical trials. The clinical sites will provide direct access to study-related source data/documents and reports for the purpose of monitoring and auditing by JJVC and for inspection by local and regulatory authorities.

17. MONITORING

The study monitors will maintain close contact with the Principal Investigator and the Investigator's designated clinical site personnel. The monitor's responsibilities will include:

- Ensuring that the investigation is being conducted according to the protocol, any subsequent amendments, and regulatory requirements are maintained
- Ensuring the rights and wellbeing of subjects are protected
- Ensuring adequate resources, including facilities, laboratories, equipment, and qualified clinical site personnel
- Ensuring that protocol deviations are documented with corrective action plans, as applicable
- Ensuring that the clinical site has sufficient test article and supplies
- Clarifying questions regarding the study
- Resolving study issues or problems that may arise

- Reviewing of study records and source documentation verification in accordance with the monitoring plan

18. ETHICAL AND REGULATORY ASPECTS

18.1. Study-Specific Design Considerations

Potential subjects will be fully informed of the risks and requirements of the study and, during the study, subjects will be given any new information that may affect their decision to continue participation. Subjects will be told that their consent to participate in the study is voluntary and may be withdrawn at any time with no reason given and without penalty or loss of benefits to which they would otherwise be entitled. Only subjects who are fully able to understand the risks, benefits, and potential adverse events of the study, and provide their consent voluntarily will be enrolled.

18.2. Investigator Responsibility

The Principal Investigator is responsible for ensuring that the clinical study is performed in accordance with the signed agreement, the investigational plan, Section 4 of the ICH E6 guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles of the Declaration of Helsinki 64th WMA General Assembly 2013 and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with Section 8 of the ICH E6 guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements.

18.3. Independent Ethics Committee or Institutional Review Board (IEC/IRB)

Before the start of the study, the Investigator (or Sponsor when applicable) will provide the IEC/IRB with current and complete copies of the following documents (where applicable):

- Final protocol and, if applicable, amendments
- Sponsor-approved informed consent form (and any other written materials to be provided to the subjects)
- Investigator's Brochure (or equivalent information) and amendments
- Sponsor-approved subject recruitment materials
- Information on compensation for study-related injuries or payment to subjects for participation in the study
- Investigator's curriculum vitae, clinical licenses, or equivalent information (unless not required, as documented by IEC/IRB)
- Information regarding funding, name of the Sponsor, institutional affiliations, other potential conflicts of interest, and incentives for subjects
- Any other documents that the IEC/IRB requests to fulfill its obligation

This study will be undertaken only after IEC/IRB has given full approval of the final protocol, amendments (if any), the informed consent form, applicable recruiting materials,

and subject compensation programs, and the Sponsor has received a copy of this approval. This approval letter must be dated and must clearly identify the documents being approved.

During the study the Investigator (or Sponsor when applicable) will send the following documents to the IEC/IRB for their review and approval, where appropriate:

- Protocol amendments
- Revision(s) to informed consent form and any other written materials to be provided to subjects
- If applicable, new or revised subject recruitment materials approved by the Sponsor
- Revisions to compensation for study-related injuries or payment to subjects for participation in the study
- Investigator's Brochure amendments or new edition(s)
- Summaries of the status of the study (at least annually or at intervals stipulated in guidelines of the IEC/IRB)
- Reports of adverse events that are serious, unanticipated, and associated with the test articles, according to the IRB's requirements
- New information that may adversely affect the safety of the subjects or the conduct of the study
- Major protocol deviations as required by the IEC/IRB
- Report of deaths of subjects under the Investigator's care
- Notification if a new Investigator is responsible for the study at the clinical site
- Any other requirements of the IEC/IRB

For protocol amendments that increase subject risk, the amendment and applicable informed consent form revisions must be submitted promptly to the IEC/IRB for review and approval before implementation of the change(s).
At least once a year, the IEC/IRB will review and reapprove this clinical study. This request should be documented in writing.

At the end of the study, the Investigator (or Sponsor where required) will notify the IEC/IRB about the study completion. Documentation of this notification must be retained at the clinical site and a copy provided to the CRO or Sponsor as applicable.

18.4. Informed Consent

Each subject must give written consent according to local requirements after the nature of the study has been fully explained. The consent form must be signed before performance of any study-related activity. The consent form that is used must be approved by both the Sponsor and by the reviewing IEC/IRB. The informed consent is in accordance with principles that originated in the Declaration of Helsinki, current ICH and GCP guidelines, applicable regulatory requirements, and Sponsor policy.

Before entry into the study, the Investigator or an authorized member of the clinical site personnel must explain to potential subject the aims, methods, reasonably anticipated benefits, and potential hazards of the study, and any discomfort it may entail. Subjects will be

informed that their participation is voluntary and that they may withdraw consent to participate at any time.

The subject will be given sufficient time to read the informed consent form and the opportunity to ask questions. After this explanation and before entry into the study, consent should be appropriately recorded by means of the subject's dated signature. After having obtained the consent, a copy of the informed consent form must be given to the subject.

18.5. Privacy of Personal Data

The collection, processing and disclosure of personal data and medical information related to the Study Subject, and personal data related to Principal Investigator and any clinical site personnel (eg, name, clinic address and phone number, curriculum vitae) is subject to compliance with the Data Protection Act of 1998 and other applicable personal data protection and security laws and regulations. Appropriate measures will be employed to safeguard these data, to maintain the confidentiality of the person's related health and medical information, to properly inform the concerned persons about the collection and processing of their personal data, to grant them reasonable access to their personal data and to prevent access by unauthorized persons.

All information obtained during the course of the investigation will be regarded as confidential. All personal data gathered in this trial will be treated in strictest confidence by Investigators, monitors, Sponsor's personnel and IEC/IRB. No data will be disclosed to any third party without the express permission of the subject concerned, with the exception of Sponsor personnel (monitor, auditor), IEC/IRB and regulatory organizations in the context of their investigation related activities that, as part of the investigation will have access to the CRFs and subject records.

The collection and processing of personal data from subjects enrolled in this study will be limited to those data that are necessary to investigate the efficacy, safety, quality, and utility of the investigational product(s) used in this study.

These data must be collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations. The Sponsor ensures that the personal data will be:

- processed fairly and lawfully
- collected for specified, explicit, and legitimate purposes and not further processed in a way incompatible with these purposes
- adequate, relevant, and not excessive in relation to said purposes
- accurate and, where necessary, kept current

Explicit consent for the processing of personal data will be obtained from the participating subject before collection of data. Such consent should also address the transfer of the data to other entities and to other countries.

The subject has the right to request through the Investigator access to his personal data and the right to request rectification of any data that are not correct or complete. Reasonable steps

should be taken to respond to such a request, taking into consideration the nature of the request, the conditions of the study, and the applicable laws and regulations.

Appropriate technical and organizational measures to protect the personal data against unauthorized disclosures or access, accidental or unlawful destruction, or accidental loss or alteration must be put in place. Sponsor personnel whose responsibilities require access to personal data agree to keep the identity of study subjects confidential

19. STUDY RECORD RETENTION

In compliance with the ICH/GCP guidelines, the Investigator/Institution will maintain all CRFs and all subject records that support the data collected from each subject, as well as all study documents as specified in ICH/GCP Section 8, Essential Documents for the Conduct of a Clinical Trial, and all study documents as specified by the applicable regulatory requirement(s). The Investigator/Institution will take measures to prevent accidental or premature destruction of these documents.
Essential documents must be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents will be retained for a longer period if required by the applicable regulatory requirements or instructed by the Sponsor. It is the responsibility of the Sponsor to inform the Investigator/Institution as to when these documents no longer need to be retained.

If the responsible Investigator retires, relocates, or for other reasons withdraws from the responsibility of keeping the study records, custody must be transferred to a person who will accept the responsibility. The Sponsor must be notified in writing of the name and address of the new custodian. Under no circumstance shall the Investigator relocate or dispose of any study documents before having obtained written approval from the Sponsor.

If it becomes necessary for the Sponsor or the appropriate regulatory authority to review any documentation relating to this study, the Investigator must permit access to such reports.
If the Investigator has a question regarding retention of study records, he/she should contact JJVC.

20. FINANCIAL CONSIDERATIONS

Remuneration for study services and expenses will be set forth in detail in the Investigator's Research Agreement. The Research Agreement will be signed by the Principal Investigator and a JJVC management representative prior to study initiation.

Case Report Forms will be completed in real time according to the study procedures specified in the study protocol. Case Report Forms should be completed and reviewed and signed as applicable by the Investigator within 3 days of visit completion. Data queries must be addressed with complete responses within 3 days of generation. JJVC reserves the right to withhold remuneration until these activities are addressed.

JJVC reserves the right to withhold remuneration for costs associated with protocol violations such as:

- Continuing an ineligible subject in the study
- Scheduling a study visit outside the subject's acceptable visit range

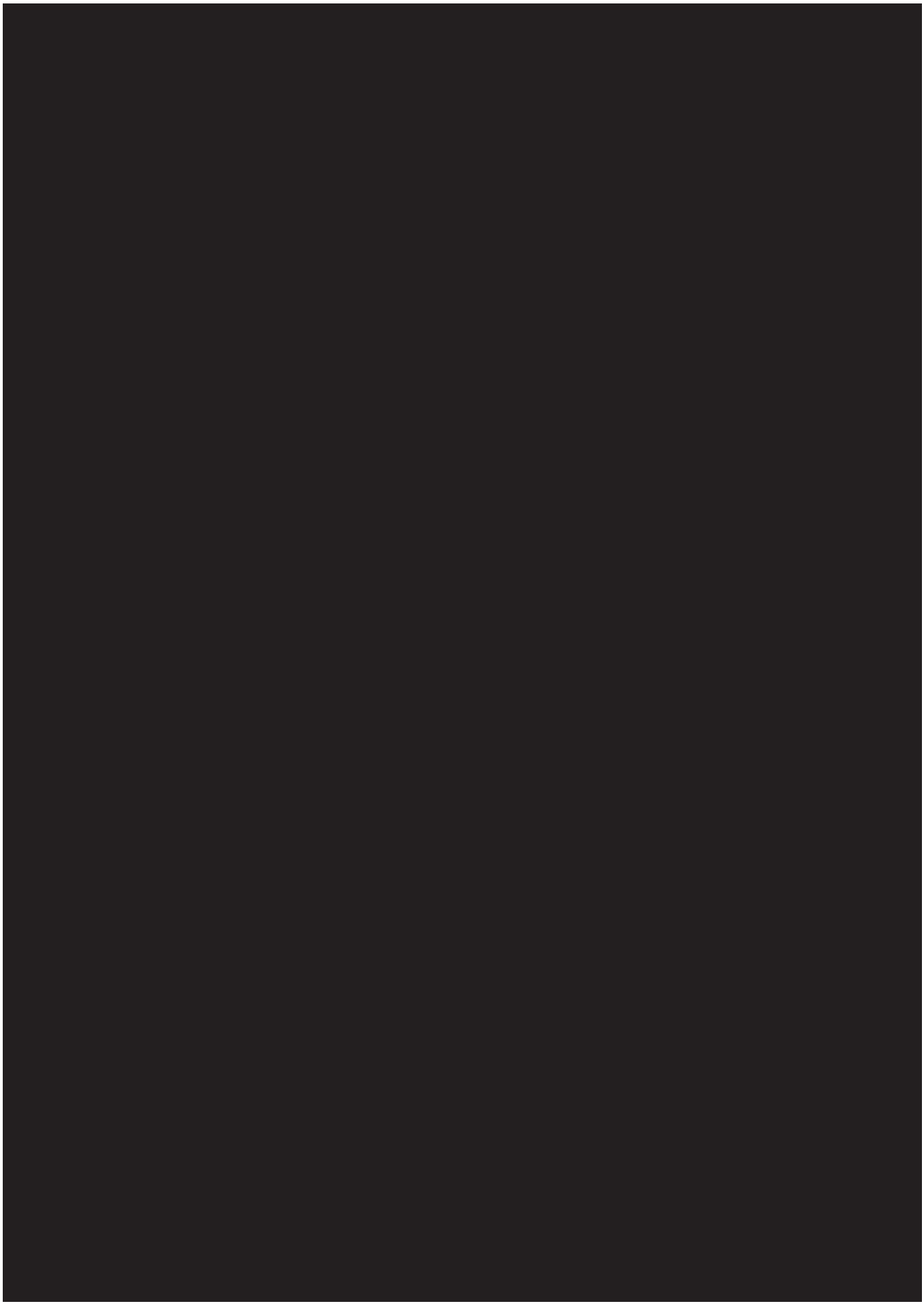
21. PUBLICATION

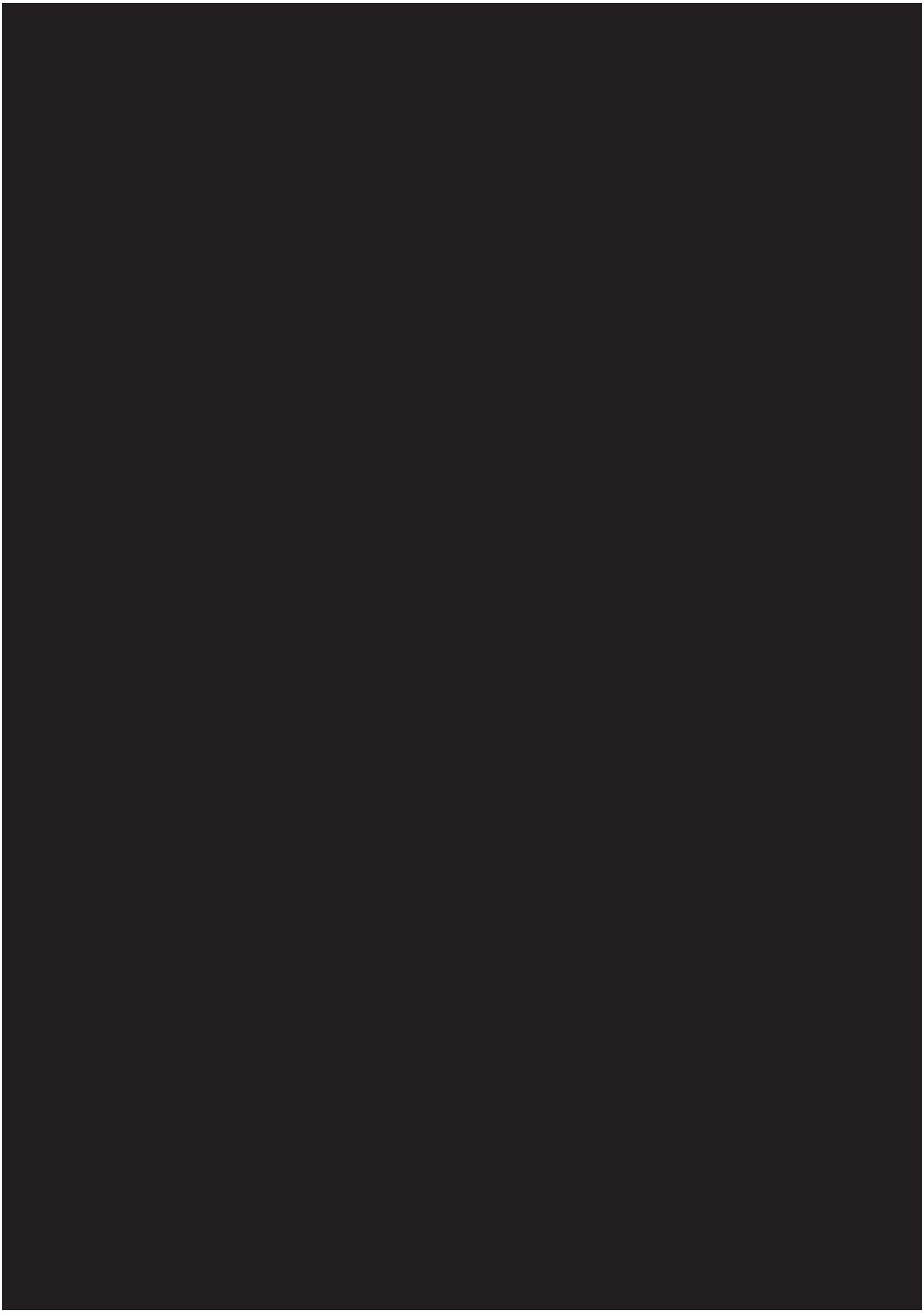
This study will be registered on ClinicalTrials.gov.

22. REFERENCES

1. Harris MG, Sarver MD and Polse KA. Patient response to thin hydrogel contact lenses. J Am Optom Assoc. 1977 Mar;(48)3:295-299.
2. Keselman HJA, J.; Kowalchuk, R. K.; and Wolfinger, R. D. A Comparison of Two Approaches for Selecting Covariance Structures in the Analysis of Repeated Measures. Communications in Statistics—Simulation and Computation. 1998(27):591–604.

APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)





APPENDIX B: PATIENT INSTRUCTION GUIDE

PATIENT INSTRUCTION GUIDE

Daily Disposable Wear

Soft (hydrophilic) Contact Lenses

Study CR-5935

TABLE OF CONTENTS

INTRODUCTION

About This Booklet:

The information and instructions contained in this booklet apply only to your study contact lenses.

For your eye health, it is important that your contact lenses be worn only as directed by your Study Investigator. Your Study Investigator should be kept fully aware of your medical history and will develop a total program of care based on the study and your specific needs. He or she will review with you all instructions for lens handling, including how to safely and easily open the packaging. You will also be taught how to properly insert and remove lenses. This booklet will reinforce those instructions.

If you have any questions, always ask your Study Investigator.

A "Glossary of Commonly Used Terms" is included for your reference. This contains definitions of medical and technical terminology used in this booklet. In addition, a "Symbols Key" provides an explanation of symbols that may appear on the lens packaging.

About Your Lenses and Contact Lens Wear:

Your contact lenses are made from a water loving (hydrophilic) material that has the ability to absorb water, making the lenses soft and flexible. The lenses are tinted to improve visibility for handling and may also contain an ultraviolet (UV) radiation absorbing ingredient to block UV radiation.

You should always have glasses or your own contact lenses available.

SYMBOLS KEY

The following symbols may appear on the label or carton:

Symbol	*Description*
	Consult Instructions for Use
	Date of Manufacture
	Manufactured by or in
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CYL	Cylinder
AXIS	Axis
LOW	Low ADD
MID	Medium ADD
HIGH	HIGH ADD
	Quality System Certification Symbol
	UV-Blocking
	Fee Paid for Waste Management
	CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner

GLOSSARY OF COMMONLY USED TERMS

Term	*Definition*
Astigmatism	A condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape, causing the visual image to be out of focus (blurred)
Conjunctivitis	Inflammation of the membrane that lines the eyelids and the white part of the eye
Cornea	Clear center part of the eye
Corneal Ulcer	A sore or lesion on the cornea
Inflammation	Swelling, redness, and pain

POTENTIAL BENEFITS

The study contact lenses might help correct your eyesight while you are wearing them, but there is no guarantee that this study will help you. Your eyesight might not be corrected by the study contact lenses or might get worse while you are in this study. Information from this study may help researchers come up with new treatments to help others in the future.

Your study lenses may contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

WARNING: UV ABSORBING CONTACT LENSES are not substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

Note: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Study Investigator for more information.

Your Study Investigator will determine your wearing schedule (how long you should wear your lenses).

REASONS YOU SHOULD NOT WEAR THE STUDY LENSES (PARTICIPATION CRITERIA)

- You have abnormalities of the cornea that could become problems for you if you wear contact lenses. These abnormalities include:
    - Corneal edema (swelling of the cornea or clear covering of the eye)
    - Corneal vascularization (small blood vessels growing into the cornea)
    - Corneal staining (defect on the corneal surface)
    - Corneal distortion (irregular surface of the eye)
    - Bulbar Injection (redness of the white of the eye)
- You have eyelid abnormalities (such as bumps on the inside of the upper eyelid) that might interfere with contact lens wear
- You have entropion (eyelid turns inward), ectropion (eyelid turns outward), extrusion (eyelid thrusting out of the socket), chalazia (bump on the eyelid), recurrent stye, dry eye, glaucoma, or history of corneal erosions
- Any previous or planned eye surgeries (for example radial keratometry, PRK, LASIK, lid procedures, cataract surgery, retinal surgery)
- You have a history of a binocular vision abnormality, strabismus (crossed eyes) or amblyopia (lazy eye)
- Any other corneal or ocular abnormality that would not allow you to wear contacts
- You have any active eye infection or inflammation (such as conjunctivitis or “pink eye”)
- You have eye or general body allergies (like seasonal allergies) that may interfere with contact lens wear
- You use medication that may interfere with contact lens wear
- Use of any ocular medication, except for rewetting drops
- You are a woman who is currently pregnant or is breastfeeding
- You currently have diabetes
- Have a history of herpetic keratitis
- You have any infectious disease, (for example, tuberculosis, hepatitis) or immune-suppressive disease (for example, HIV)
- You have participated in any contact lens study or lens care product study in the past 30 days prior to starting this study
- You are an employee of the clinical site (for example, Investigator, Coordinator, Technician)

POSSIBLE RISKS OR DISCOMFORTS RELATED TO THE STUDY

What You Should Know About Contact Lens Wear and This Study:

The following problems may also occur when wearing contact lenses:

- Burning, stinging, and/or itching of the eyes
- A feeling like there is something in the eye (foreign body, scratched area)
- Reduced vision or temporary loss of vision due to peripheral infiltrates (white blood cells), peripheral corneal ulcers (inflammation of the cornea), and/or corneal erosion (defects in the corneal surface)
- Local or generalized edema (swelling)
- Corneal neovascularization (small blood vessels growing into the cornea)
- Corneal staining (defect in the corneal surface)
- Redness
- Tarsal abnormalities (bumps on the inside upper eye lid)
- Iritis (internal inflammation of the eye)
- Conjunctivitis (infection or inflammation of the white part of the eye or under the eyelids)
- Excessive watering, unusual eye secretions, or redness of the eye
- Poor visual acuity
- Blurred vision
- Rainbows or halos around objects
- Sensitivity to light

You should tell the study doctor or study staff about any eye discomfort, vision changes, or other eye problems you may experience during or after wearing the study contact lenses. You should continue to see your regular eye care practitioner routinely as directed.

PRECAUTIONS

For your eye health, it is important to carefully follow the handling, insertion, removal and wearing instructions in this booklet as well as those prescribed by your Study Investigator (**see "Lens Handling & Insertion" and "Lens Wearing" sections**).

General Precautions:

- **Always** contact your Study Investigator before using any medicine in your eyes.
- **Be aware** that certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness may cause dryness of the eye, increased lens awareness (feeling of the lens in the eye) or blurred vision. Always inform your Study Investigator if you experience any problems with your lenses while taking such medications. Depending on your symptoms, your Study Investigator may recommend rewetting drops that are available for use with soft contact lenses or may recommend that you stop wearing contact lenses while you are using these medications.
- **Be aware** that if you use oral contraceptives (birth control pills), you could develop changes in vision or comfort when wearing contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Ask your Study Investigator about the recommended follow-up schedule.

Who Should Know That You are Wearing Contact Lenses:

- **Inform** all of your doctors (Health Care Professionals) about being a contact lens wearer.
- **Always** inform your employer of being a contact lens wearer. Some jobs may require use equipment or may require that you not wear contact lenses.

LENS HANDLING AND INSERTION

For your eye health, it is important to carefully follow the handling, insertion, removal and wearing instructions in this booklet as well as those prescribed by your Study Investigator. If you will not or cannot always follow the recommended care procedures, you should not attempt to wear contact lenses.

Step 1: Getting Started

It is essential that you learn and use good hygiene in the care and handling of your study lenses.

Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean, dry, and free of any soaps, lotions, or creams before you handle your lenses.

Before you start:

- Always wash your hands thoroughly with a mild soap, rinse completely and dry with a lint-free towel before touching your lenses.

  DO NOT touch your contact lenses with your fingers or hands if they are not completely clean, because tiny lens scratches may occur, causing unclear vision and/or injury to your eye.

- You should avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses. These substances may come into contact with the lenses and interfere with successful wearing.

  DO NOT get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on your lenses.

Start off correctly by getting into the habit of always using proper hygiene so that they become automatic.

Step 2: Opening the Packaging

Multipack

Each multipack contains individually packaged lenses. Each lens comes in its own lens package designed specifically to keep it sterile.

Lens Package

To open an individual lens package, follow these simple steps:

DO NOT use if the sterile blister package is opened or damaged.

1. Shake the lens package and check to see that the lens is floating in the solution.
2. Peel back the foil closure to reveal the lens. By stabilizing the lens package on the table-top, you will minimize the possibility of a sudden splash.
3. Place a finger on the lens and slide the lens up the side of the bowl of the lens package until it is free of the container.

NEVER use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use.

Occasionally, a lens may stick to the inside surface of the foil when opened, or to the plastic package itself. This will not affect the sterility of the lens. It is still perfectly safe to use. Carefully remove and inspect the lens following the handling instructions.

Lens Handling Tips

- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

  DO NOT touch the lens with your fingernails.

- Develop the habit of always working with the same lens first to avoid mix-ups.
- After you have removed the lens from the packaging, examine it to be sure that it is moist, clean, and free of any nicks or tears. If the lens appears damaged, DO NOT use it. The Study Investigator will replace the lens.

  ALWAYS handle lenses carefully and avoid dropping them.

Step 3: Placing the Lens on the Eye

Remember, always start with the same eye.

Once you have opened the lens package, removed and examined the lens, follow these steps to insert the lens to your eye:

1. BE SURE THE LENS IS NOT INSIDE-OUT by following either of the following procedures:

   - Place the lens on the tip of your index finger and check its profile. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out. Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.

2. With the lens on your index finger, use your other hand to hold your upper eyelid so you won't blink.
3. Pull down your lower eyelid with the other fingers of your "inserting" hand.
4. Look up at the ceiling and gently place the lens on the lower part of your eye.
5. Slowly release your eyelid and close your eye for a moment.
6. Blink several times to center the lens.
7. Use the same technique when inserting the lens for your other eye.

There are other methods of lens placement. If the above method is difficult for you, ask your Study Investigator for an alternate method.

LENS WEARING

While wearing your lenses, remember the following important precautions:

Hazardous Conditions

- If you use aerosol (spray) products, such as hair spray, while wearing lenses, keep your eyes closed until the spray has settled.
- **Avoid** all harmful or irritating vapors and fumes while wearing lenses.

Lubricating/Rewetting Solutions

- Your Study Investigator may recommend a lubricating/rewetting solution for your use. These solutions can be used to wet (lubricate) your lenses while you are wearing them.
- **Do not** use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- **Never** rinse your lenses in water from the tap. There are two reasons for this:
    1. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
    2. You might lose your lens down the drain.

Sticking (Non-Moving) Lens

- For your eye health, it is important the lens moves freely on your eye.
- If the lens sticks (stops moving) on your eye, apply a few drops of the recommended rewetting solution. Wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, you should immediately consult your Study Investigator.

Sharing Lenses

- **Never** allow anyone else to wear your lenses. Sharing lenses greatly increases the chance of eye infections.

Adhering to the Prescribed Wearing Schedule

- **Never** wear your lenses beyond the amount of time recommended by your Study Investigator.

REMOVING YOUR LENSES

CAUTION: Always be sure the lens is on the cornea (in the center of your eye) before attempting to remove it. Determine this by covering the other eye. If vision is blurred, the lens is either on the white part of the eye or it is not on the eye at all. To locate the lens, inspect the upper area of the eye by looking down into a mirror while pulling the upper lid up. Then inspect the lower area by pulling the lower lid down.

Always remove the same lens first.

1. Wash, rinse and dry your hands thoroughly.
2. There are two recommended methods of lens removal: the Pinch Method and the Forefinger and Thumb Method. You should follow the method that is recommended by your Study Investigator.

   Pinch Method:

   Step 1. Look up, slide the lens to the lower part of the eye using the forefinger.
   Step 2. Gently pinch the lens between the thumb and forefinger.
   Step 3. Remove the lens.

   Forefinger and Thumb Method:

   Step 1. Place your hand or a towel under your eye to catch the lens.
   Step 2. Place your forefinger on the center of the upper lid and your thumb on the center of the lower lid.
   Step 3. Press in and force a blink. The lens should fall onto your hand or the towel.

   Note: The lens may come out, but remain on the eyelid, finger or thumb.

3. Remove the other lens by following the same procedure.

Always have glasses or your own contact lenses available.

Note: If these methods of removing your lens are difficult for you, ask your Study Investigator for an alternate method.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR STUDY INVESTIGATOR OR VISIT A HOSPITAL EMERGENCY ROOM RIGHT AWAY.

NOTES

Sponsored By:

Johnson & Johnson Vision Care, Inc.

7500 Centurion Parkway

Jacksonville, FL 32256

USA

Tel: 1-800-843-2020

Revision date 05/2017

[redacted]

[redacted]

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)
Not Applicable for Investigational Products

APPENDIX D: PRESBYOPIC SYMPTOMS QUESTIONNAIRE
Presbyopic Symptoms Questionnaire

1. Do you notice that you often have to hold things farther away so that you could read them?
2. Do you notice that you often have difficulty focusing on near objects (ie, experiencing blurry vision when looking at things close-up)?
3. Do you often have headaches or eyestrains, or feel fatigued, when read or conduct other near activities?
4. Do you often have difficulty reading small or fine prints, such as phone books, medicine bottles or package labels, etc?
5. Do you often have difficulty reading under dim or low light?

APPENDIX E: [redacted]

- [redacted] LIMBAL & CONJUNCTIVAL (BULBAR) REDNESS
- [redacted] EXPANDED SODIUM FLUORESCEIN CORNEAL STAINING
- [redacted] DETERMINATION OF NEAR ADD
- [redacted] LENS FITTING CHARACTERISTICS
- [redacted] SUBJECT REPORTED OCULAR SYMPTOMS
- [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS
- [redacted] BIOMICROSCOPY SCALE
- [redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION
- [redacted] TORIC FIT EVALUATION

[redacted] LIMBAL & CONJUNCTIVAL (BULBAR) REDNESS

[redacted] Limbal & Conjunctival (Bulbar) Redness

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] EXPANDED SODIUM FLUORESCEIN CORNEAL STAINING

[redacted]

Expanded Sodium Fluorescein Corneal Staining

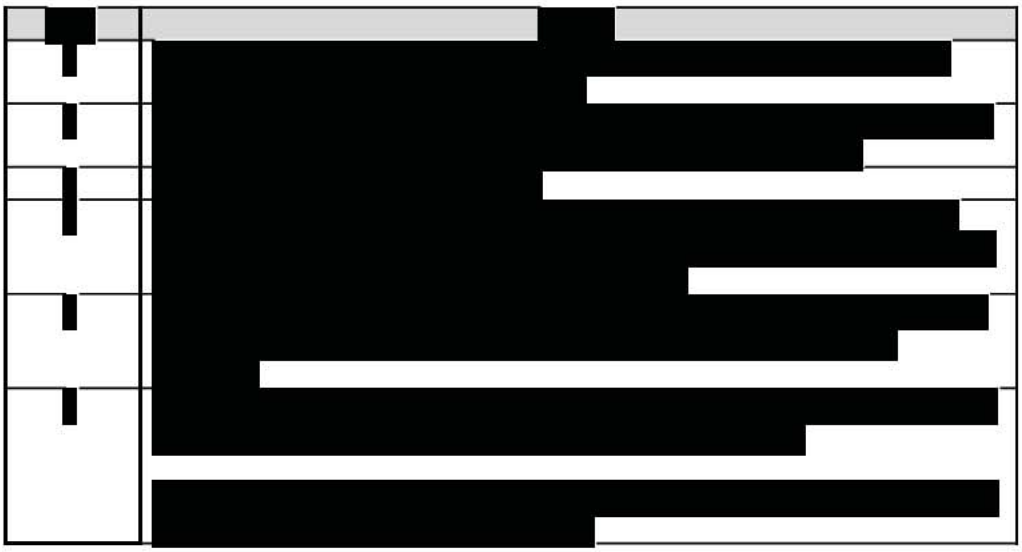
[redacted]

[redacted]

[redacted]

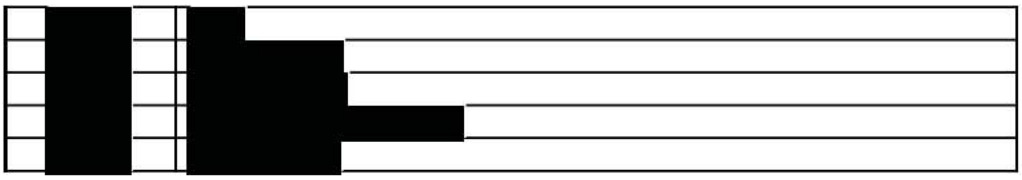
[redacted]

[redacted]



[redacted]

[redacted]



[redacted]

[redacted]

[redacted]

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

[redacted]

[redacted]

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

[redacted]

[redacted]

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

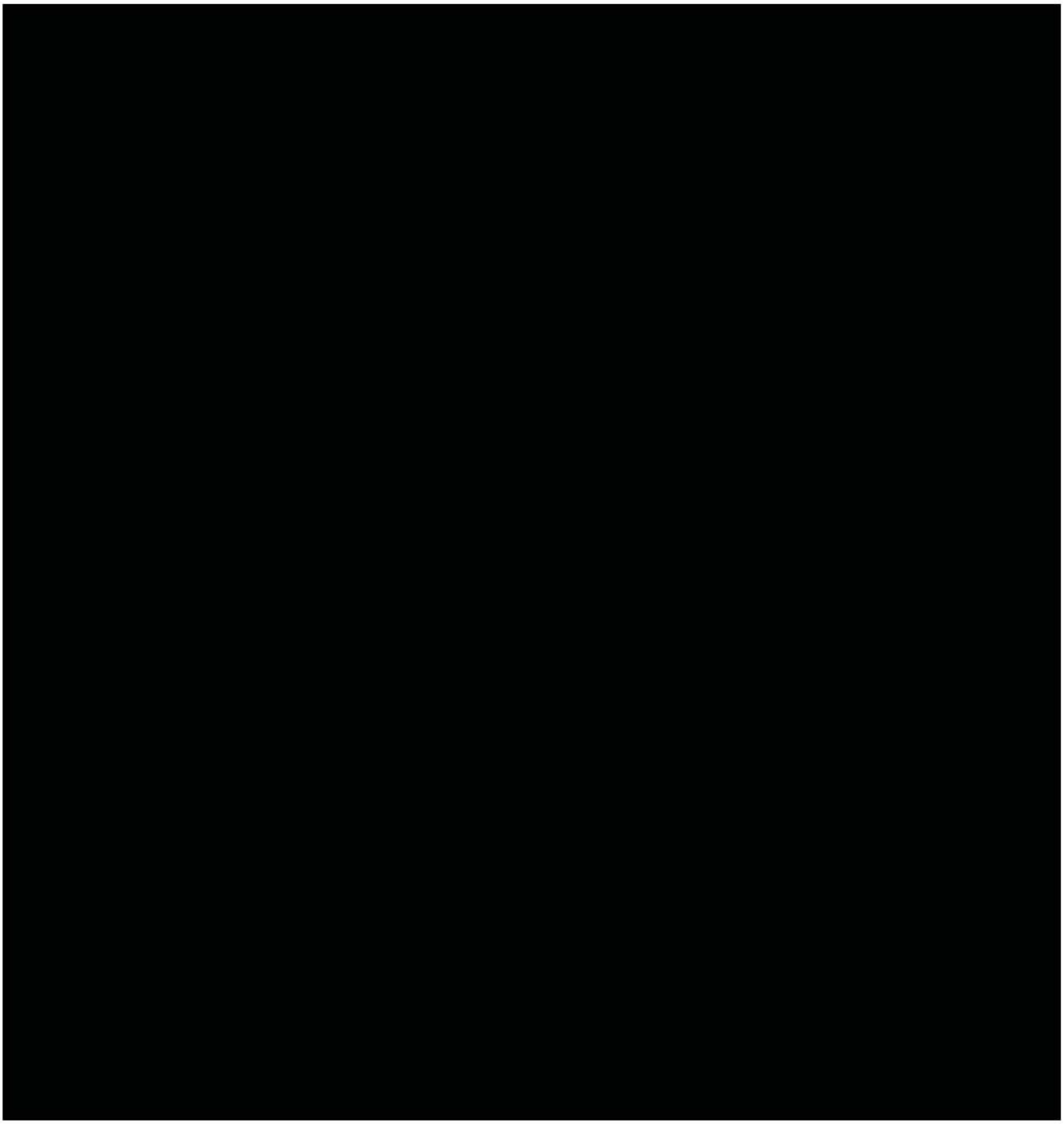
[redacted]

[redacted]

- [redacted]
- [redacted]

[redacted]

[redacted]



[redacted] DETERMINATION OF NEAR ADD

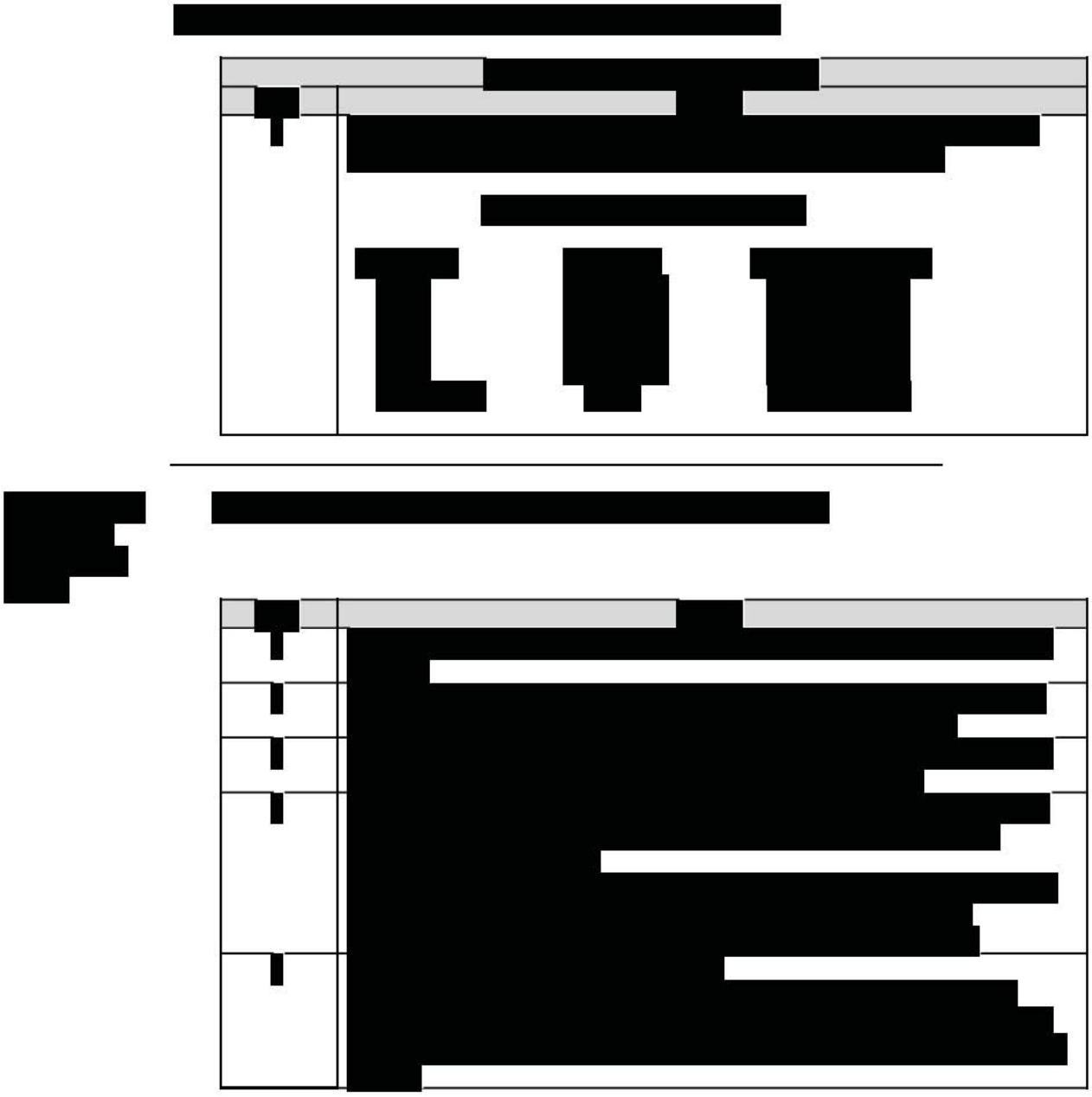
[redacted] **Determination of Near Addition**

[redacted]

[redacted]

[redacted]

[redacted]

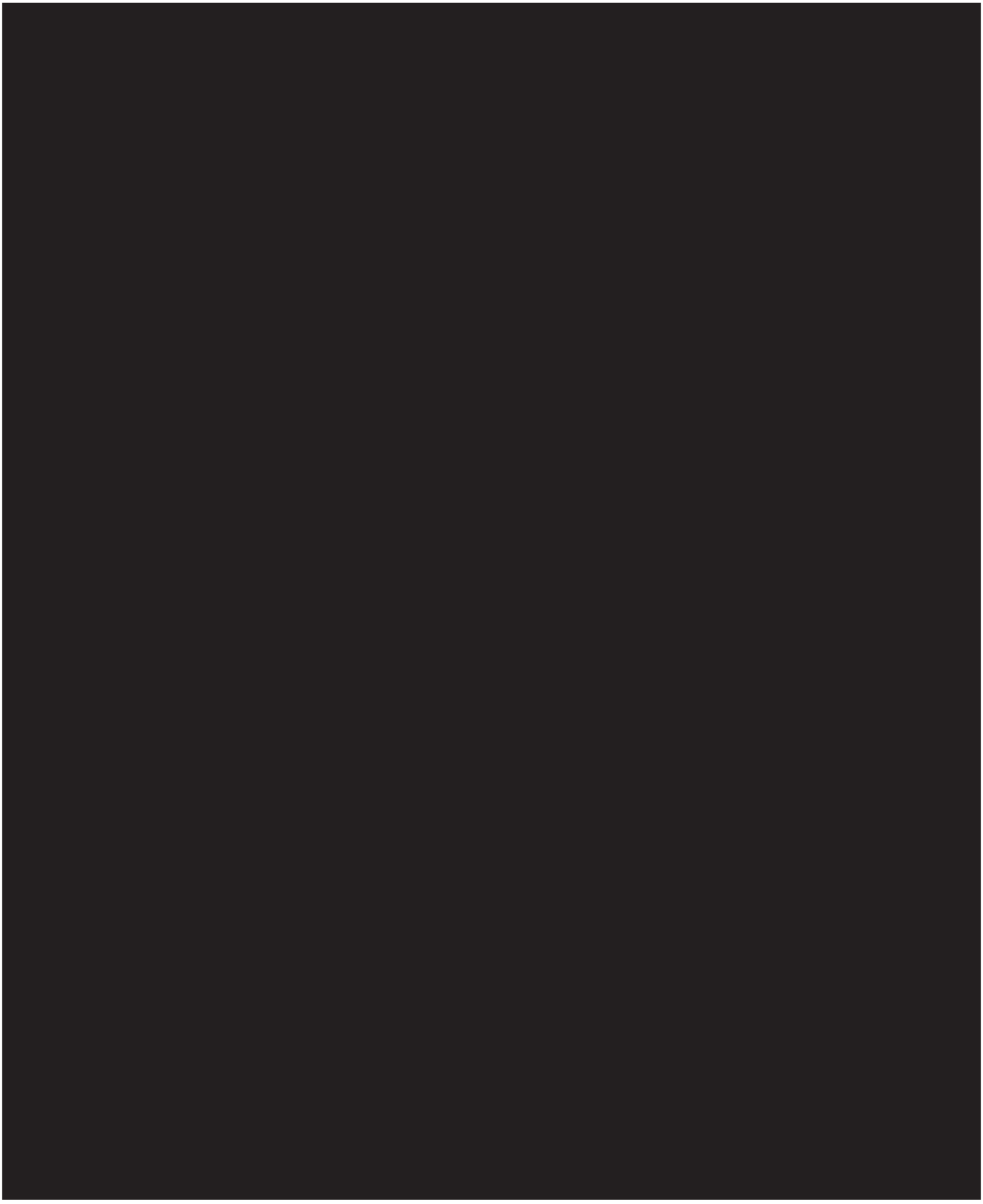


[redacted]

[redacted]

st distance, ask the patient to read the smallest line he/she can easily read.

[redacted]	[redacted]
[redacted]	[redacted] [redacted] [redacted] [redacted]
[redacted]	[redacted]
[redacted]	[redacted] B



[redacted] LENS FITTING CHARACTERISTICS

[redacted] Lens Fitting Characteristics

[redacted] [redacted]

[redacted] [redacted]

[redacted]

[redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

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

[redacted]

[redacted] [redacted]

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

[redacted] [redacted]

[redacted]

[redacted]

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

[redacted]

[redacted]

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

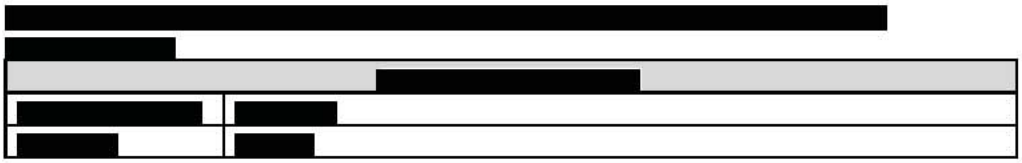
[redacted]

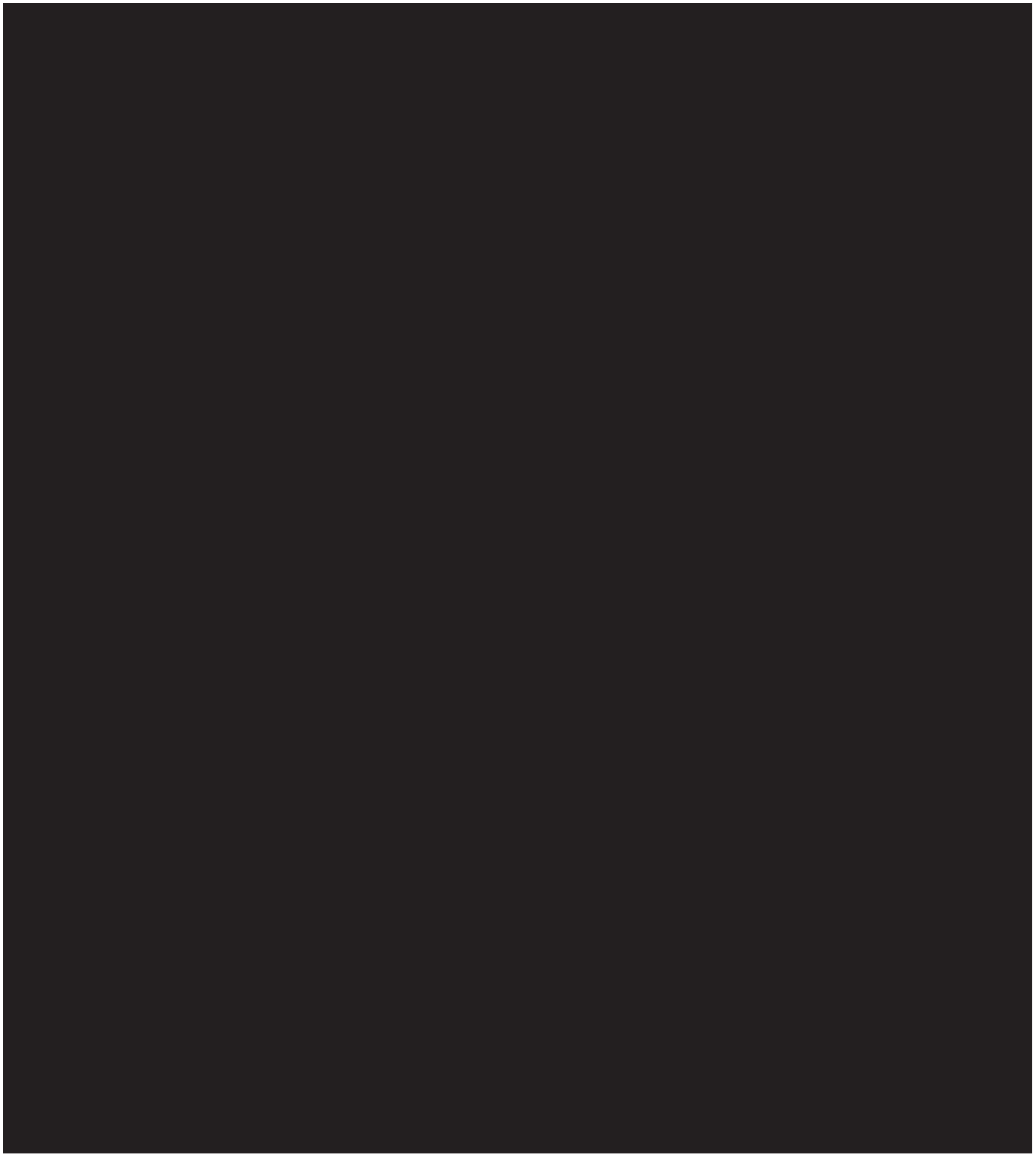
[redacted]

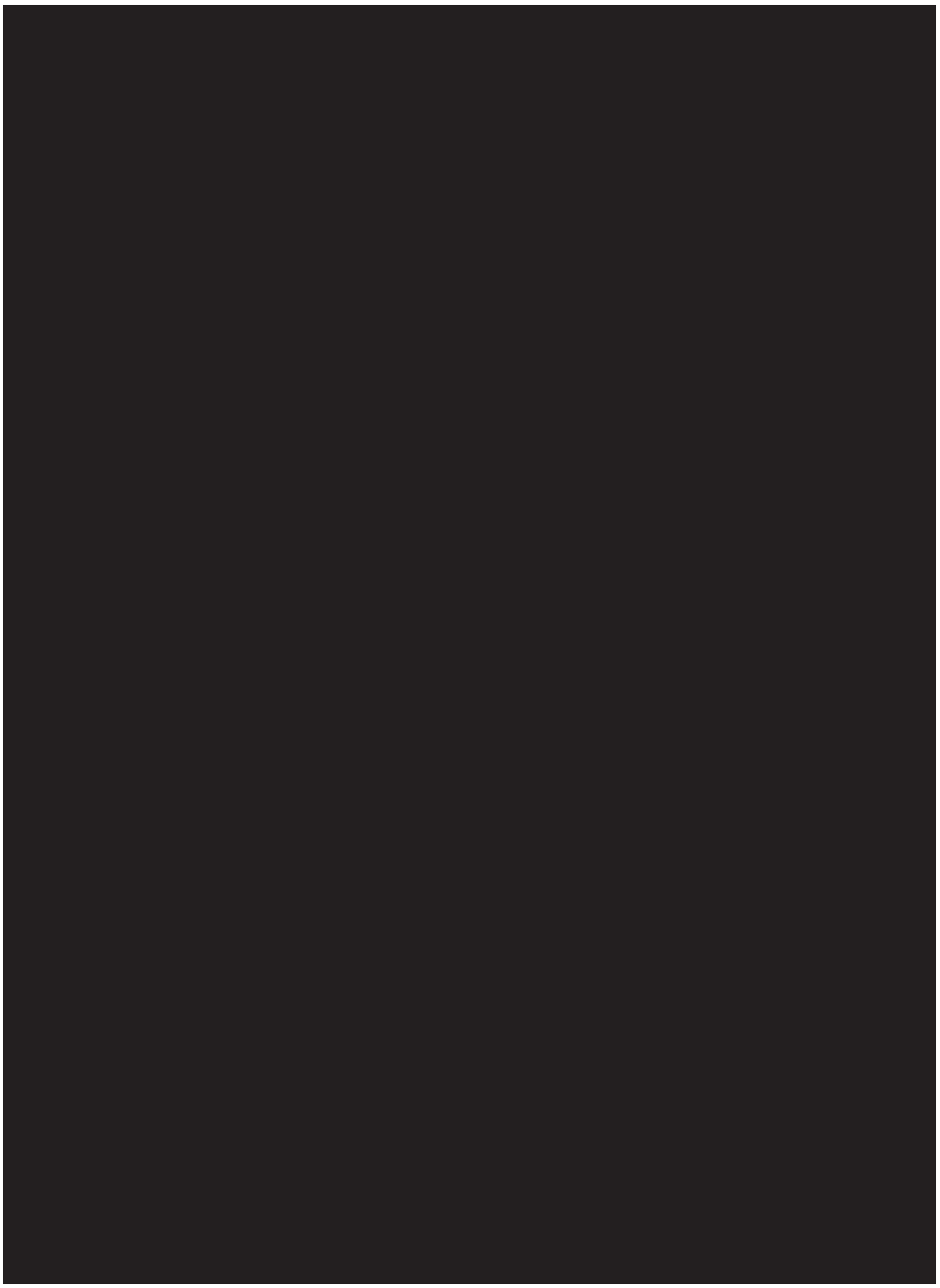
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]

[redacted]

[redacted]







[redacted] **SUBJECT REPORTED OCULAR SYMPTOMS**

[redacted] **Subject Reported Ocular Symptoms/Problems**

[redacted]

[redacted]

[redacted]

[redacted]

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

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS

[redacted] **Determination of Distance Spherocylindrical Refractions**

[redacted]

[redacted]

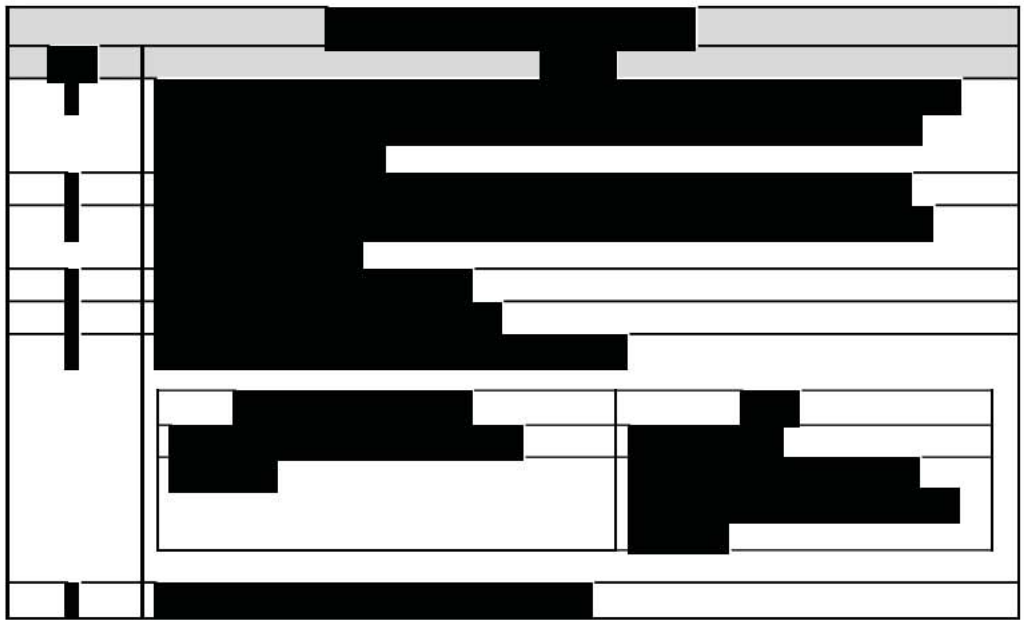
[redacted]

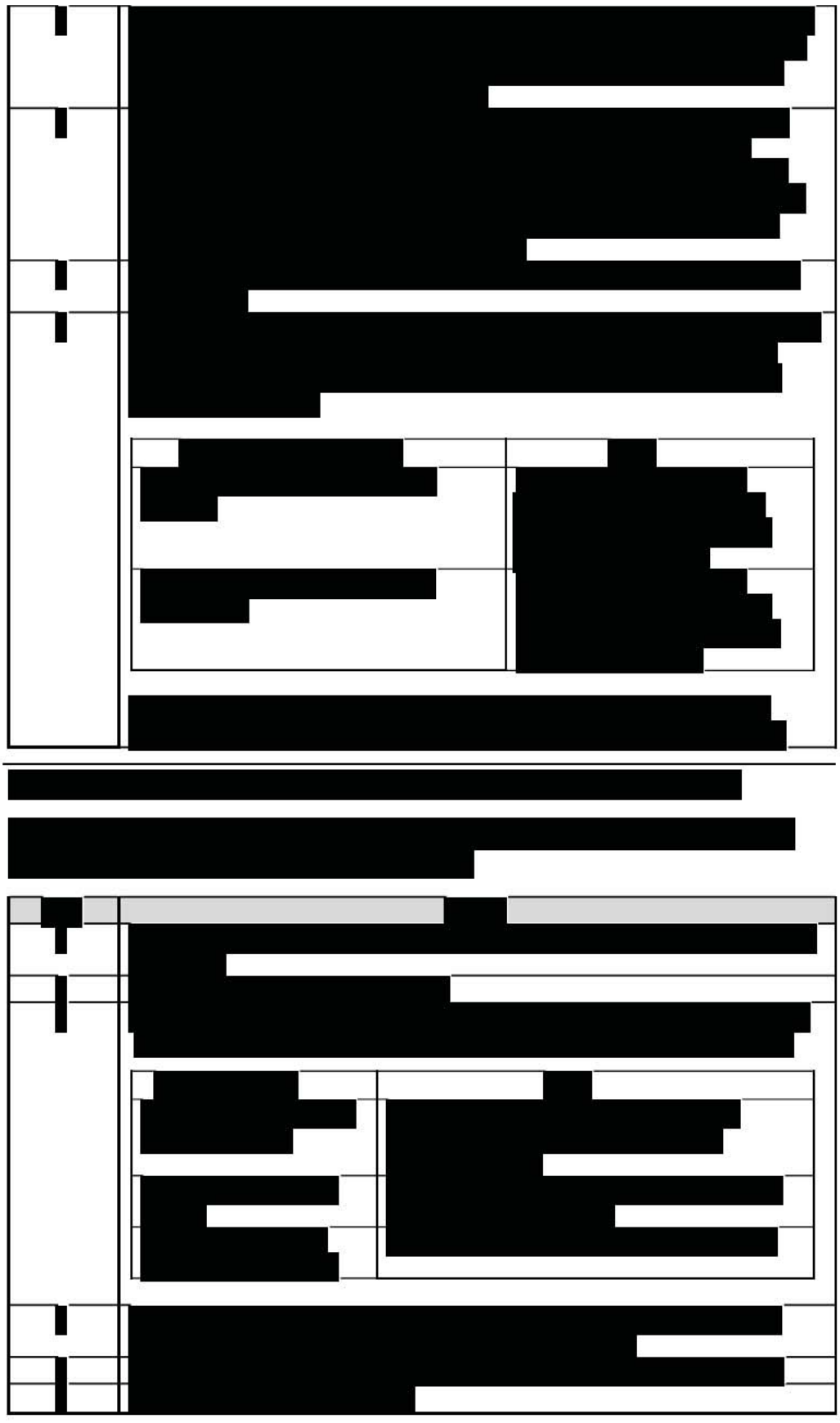
[redacted]

[redacted]

[redacted]

[redacted]





[redacted] **BIOMICROSCOPY SCALE**

[redacted]

Biomicroscopy Scale

[redacted]

[redacted]

[redacted]

[redacted]

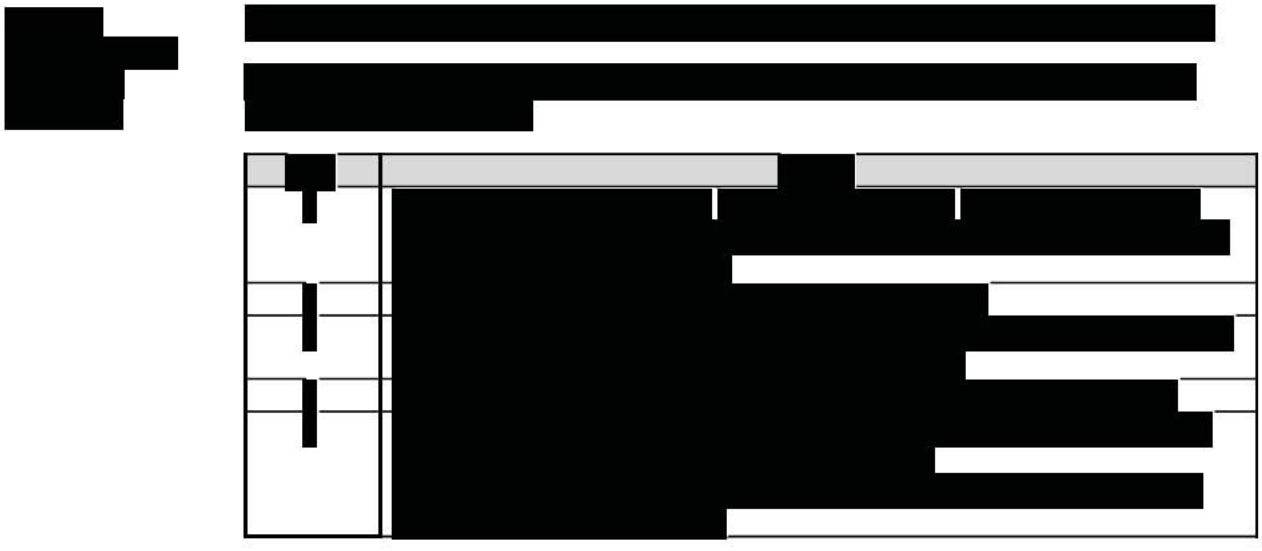
[redacted]

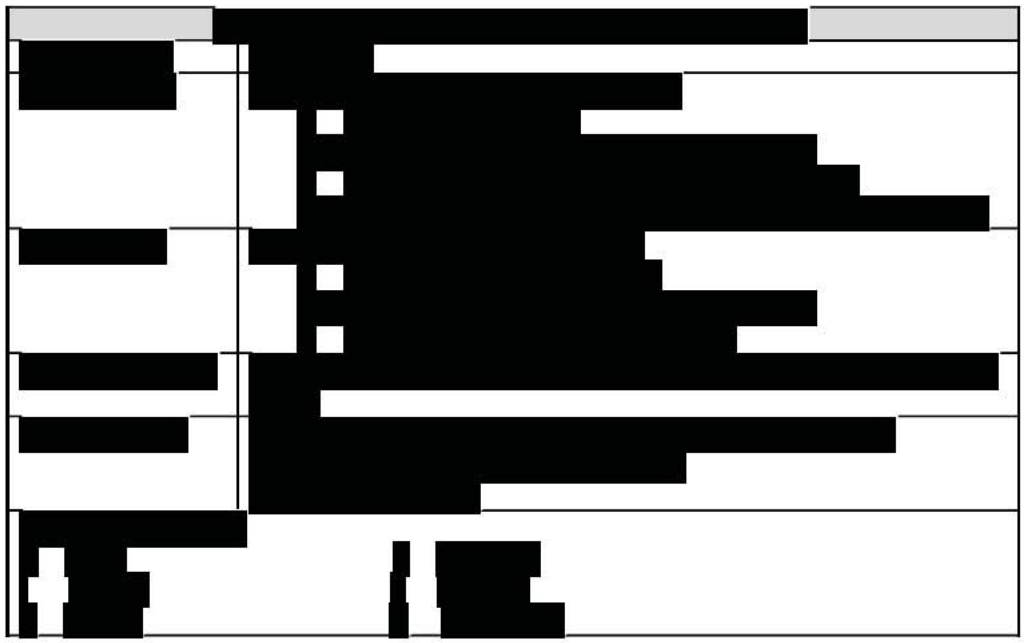
[redacted]

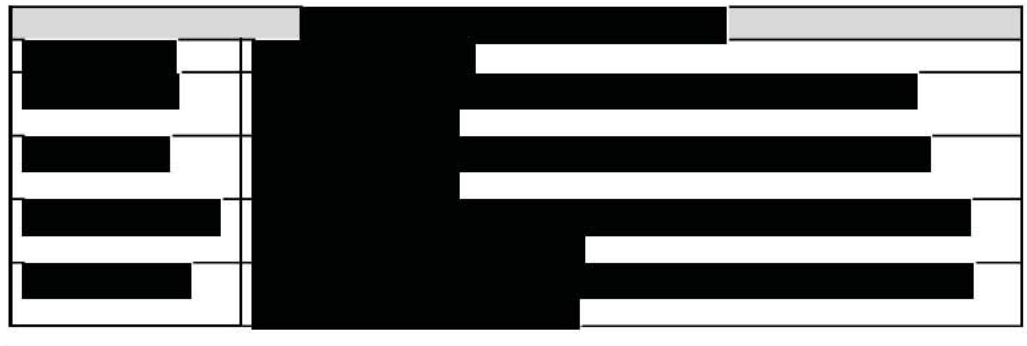
[redacted]

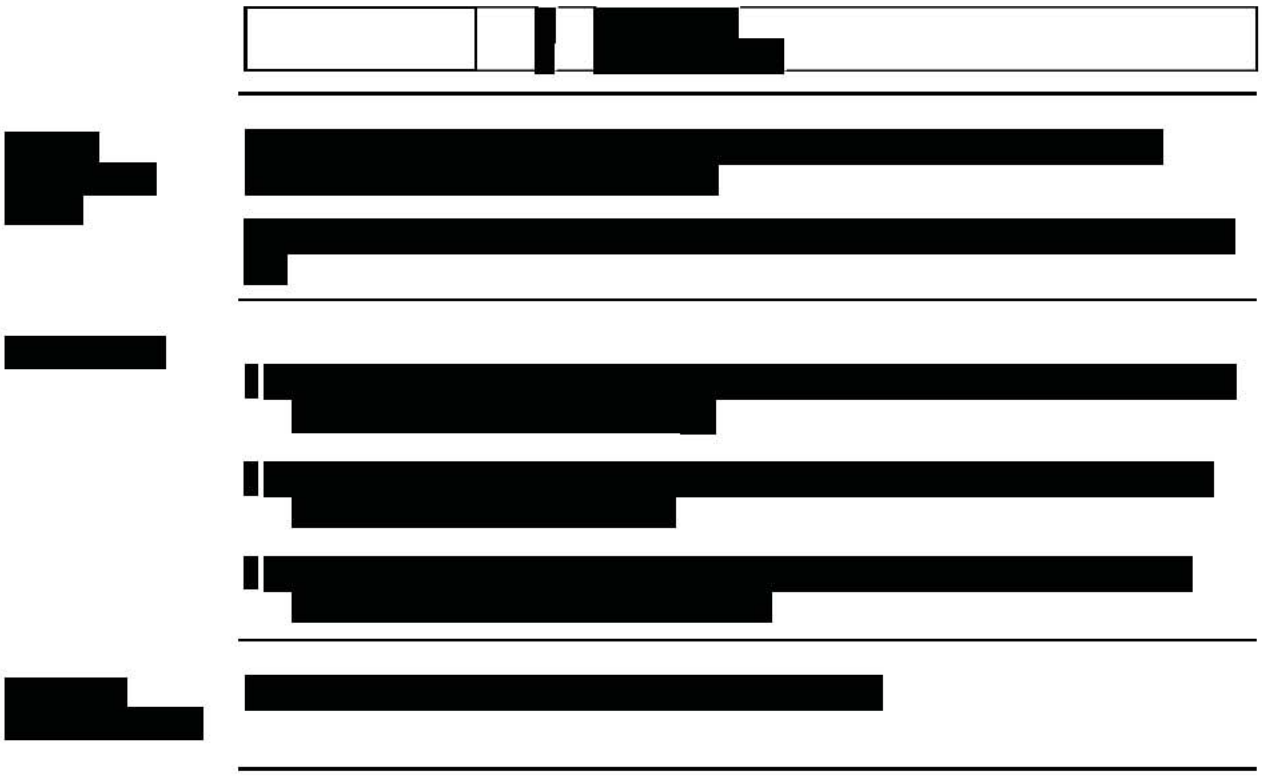
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

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

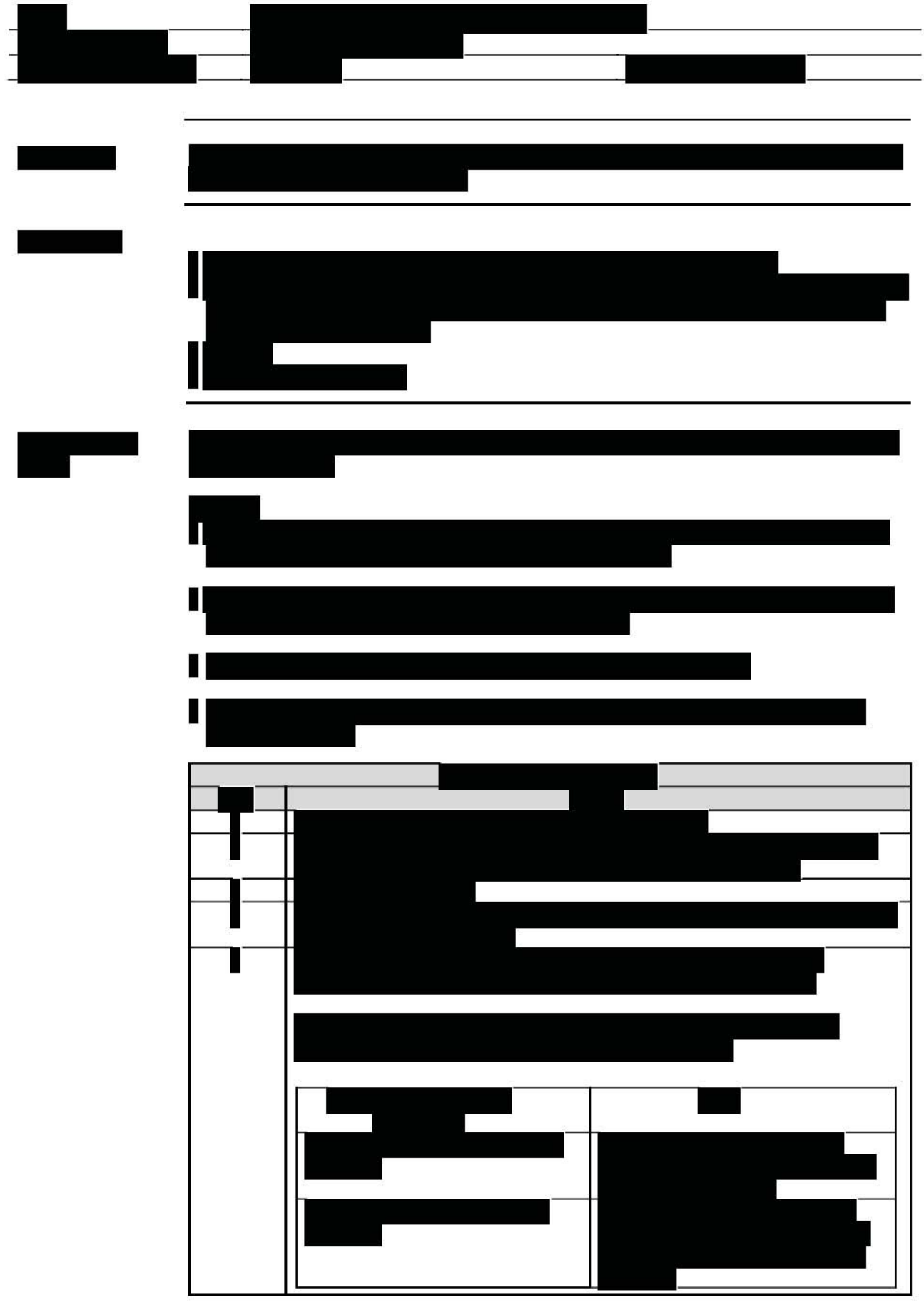


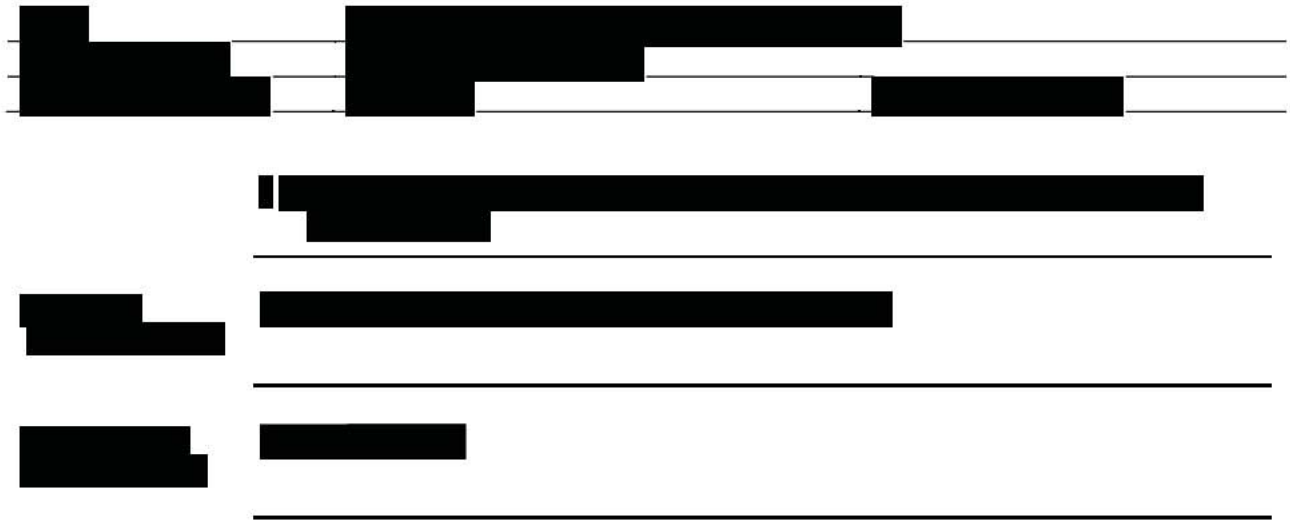


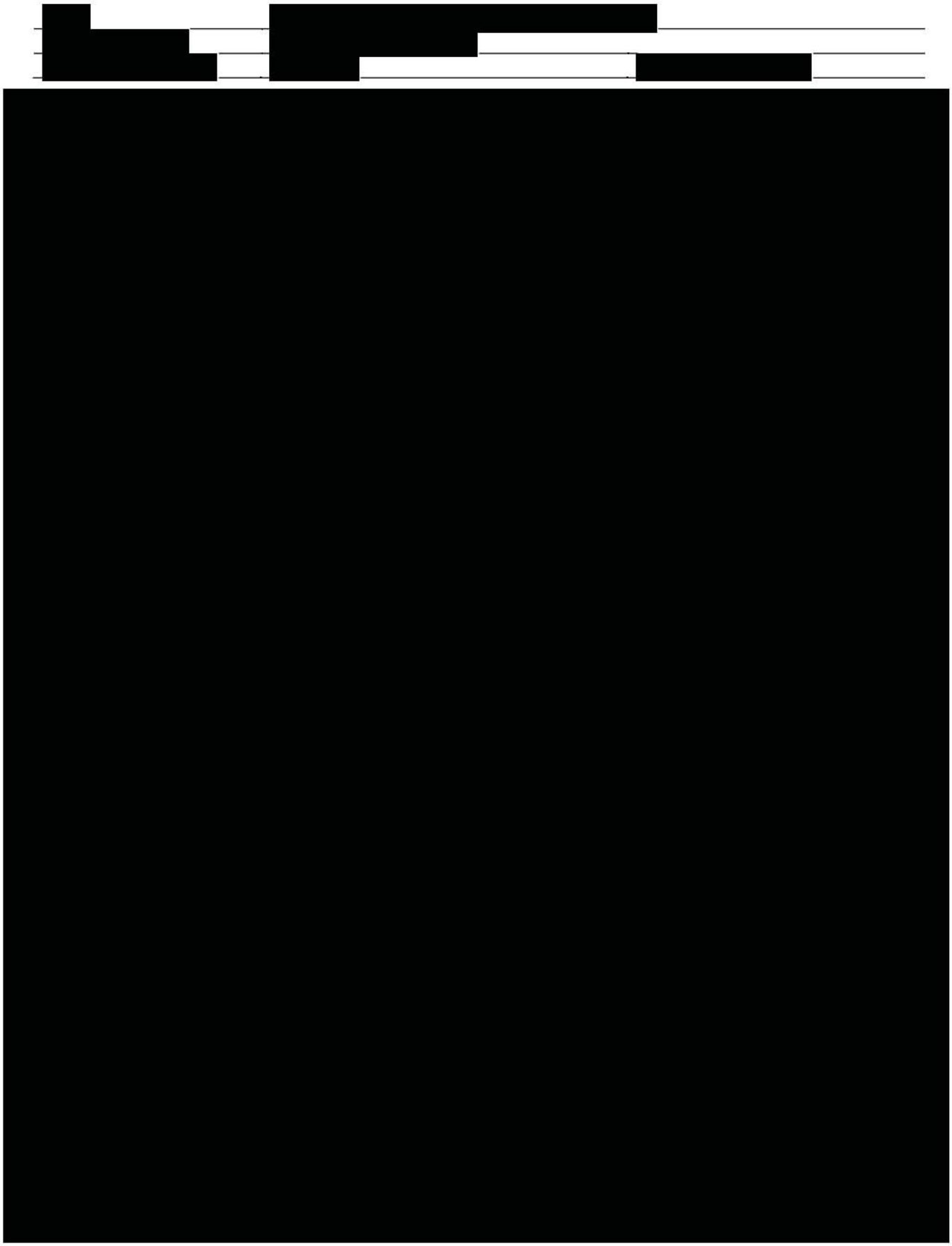




[redacted] **DISTANCE AND NEAR VISUAL ACUITY EVALUATION**







[redacted] **TORIC FIT EVALUATION**

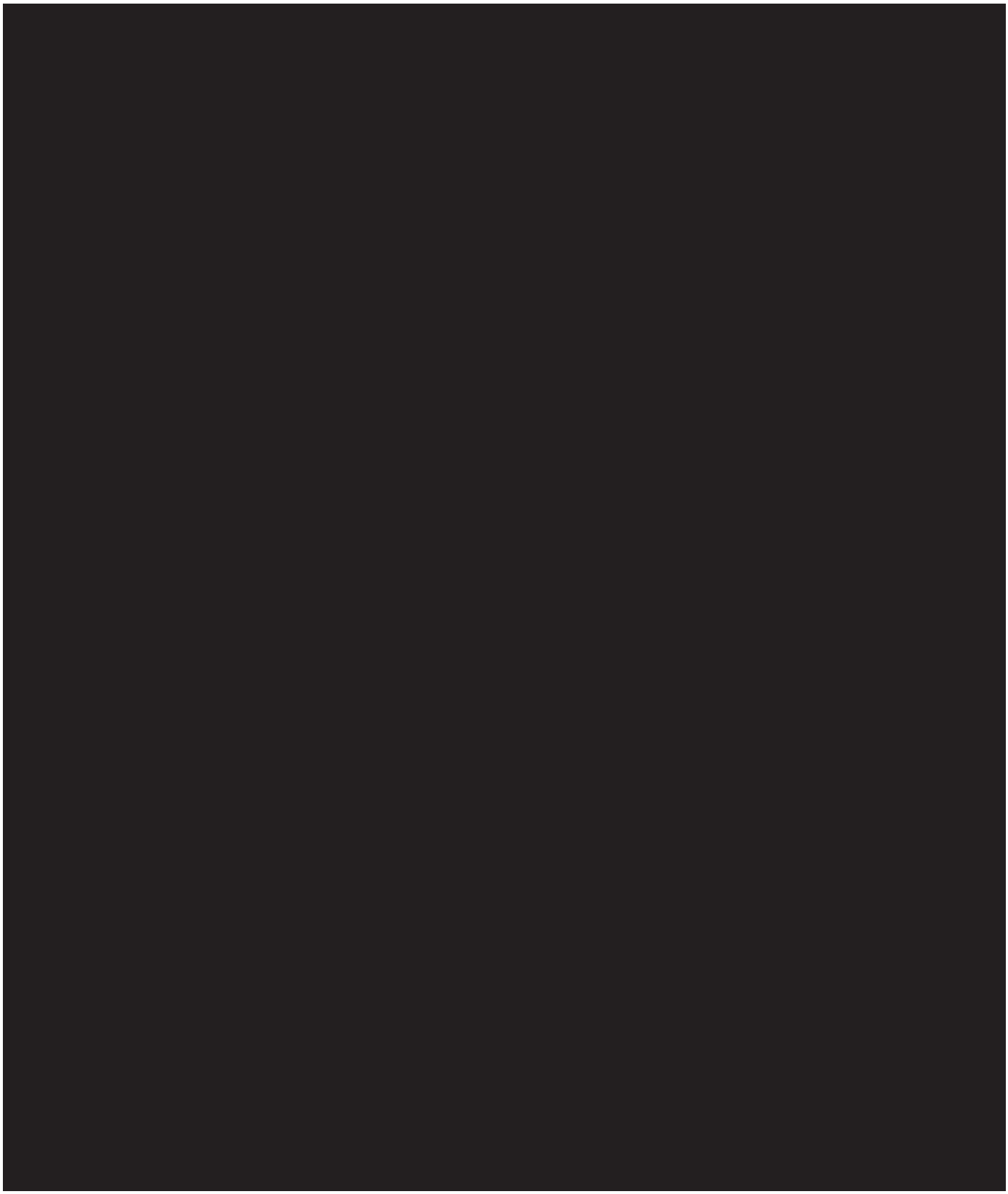
[redacted] **Toric Fit Evaluation**

[redacted]

[redacted]

[redacted]

[redacted]



PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: Handling Evaluation of Multifocal Toric Contact Lenses

Version and Date: v3.0, 31-May-2017

I have read and understand the protocol specified above and agree on its content.

I agree to conduct this study according to GCP and ICH guidelines, the Declaration of Helsinki, ISO 14155, United States (US) Code of Federal Regulations (CFR), and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. The Principal Investigator is responsible for ensuring that all clinical site personnel, including Sub-Investigators adhere to all ICH regulations and GCP guidelines regarding clinical trials during and after study completion.

I will assure that no deviation from, or changes to the protocol will take place without prior agreement from the Sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants.

I am responsible for ensuring that all clinical site personnel including Sub-Investigators adhere to all ICH regulations and GCP guidelines regarding clinical trials during and after study completion.

All clinical site personnel involved in the conduct of this study have completed Human Subjects Protection Training.

I agree to ensure that all clinical site personnel involved in the conduct of this study are informed about their obligations in meeting the above commitments.

I shall not disclose the information contained in this protocol or any results obtained from this study without written authorization.

Principal Investigator:

_____ _____

Signature Date

_____

Name and Professional Position (Printed)

Institution/Site:

_____

Institution/Site Name

_____ _____

Institution/Site Address