# Johnson & Johnson Vision Care, Inc.

# Clinical Study Protocol

## Evaluation of the JJVC Investigational Toric Multifocal Contact Lens Fitting Guide Phase II

**Protocol CR-5955**

**Version:** 2.0, Amendment 1

**Date:** 17-APR-2017

Investigational Products: JJVC Investigational etafilcon A Toric Multifocal Contact Lens and 1-Day Acuvue® Moist Brand Multifocal Contact Lens

Key Words: Multifocal, Astigmatism, etafilcon A, Non-Dispensing, Daily-wear, Presbyopia

**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[1], the Declaration of Helsinki[2], and all applicable regulatory requirements.

**Confidentiality Statement:**

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## PROTOCOL TITLE, NUMBER, VERSION

Title: Evaluation of the JJVC Investigational Toric Multifocal Contact Lens Fitting Guide Phase II
Protocol Number: CR-5955
Version: 2.0, Amendment 1
Date: 17-APR-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
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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 | Thomas R. Karkkainen, OD, MS, FAAO<br>Sr. Principal Research Optometrist | DATE |
| Clinical Operations Manager | Cynthia Marsh, CPOA<br>Clinical Operations Manager | DATE |
| Biostatistician | Jing Xu, PhD<br>Biostatistician IV | DATE |
| Data Management | Randall Paulk<br>Clinical Project Manager-Data and Systems | DATE |
| Reviewed | No Fellow Review Required<br>Noel Brennan, MScOptom, PhD, FAAO<br>Clinical Research Fellow | DATE |
| Approver | Khaled Chehab<br>Presbyopia Platform Sr. Manager | DATE |

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## CHANGE HISTORY

| Version | Originator | Description of Change(s) and Section Number(s) Affected | Date |
|---|---|---|---|
| 1.0 | Tom Karkkainen | Original Protocol | 14-APR-2017 |
| 2.0 | Tom Karkkainen | Throughout protocol-updated version, date and added page numbering.<br><br>Section 6-added two additional over-label protocol numbers to Table. | 17-APR-2017 |

**SYNOPSIS**

| | |
|---|---|
| Protocol Title | Evaluation of the JJVC Investigational Toric Multifocal Contact Lens Fitting Guide Phase II |
| Sponsor | JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256 |
| Clinical Phase | Phase 2 |
| Trial Registration | This study will be registered on ClinicalTrials.gov by the Sponsor |
| Test Article(s) | Investigational Products: etafilcon A Toric Multifocal Contact Lens<br>Marketed Products:1-Day Acuvue® Moist Brand Multifocal Contact Lens |
| Wear and Replacement Schedules | Wear Schedule: Daily Wear<br>Replacement Schedule: None- Non-dispensing study |
| Objectives | The primary objective of this study is an evaluation of the JJVC Investigational Toric Multifocal and 1-Day Acuvue® Moist Brand Multifocal Contact Lens fitting guides by Eye Care Providers (ECPs). |

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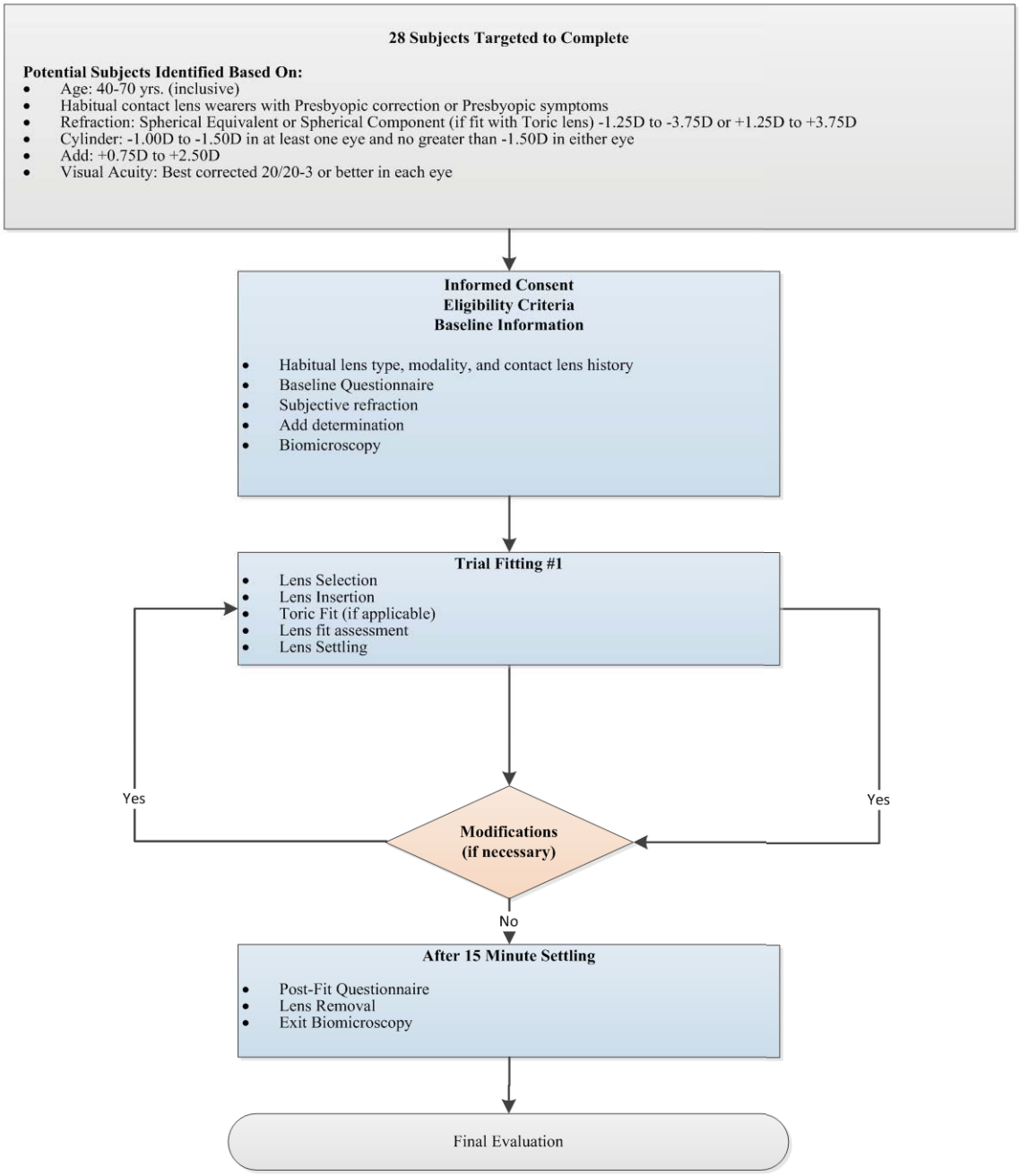
| | |
|---|---|
| Study Endpoints | Primary endpoint: The maximum number of lens modifications for both eyes required by the ECP to optimize the lenses for vision.<br>Secondary endpoint:<br>1. Subjective feedback from the ECP on the fitting guide process (i.e. intuitive nature of the fitting steps, adequate amount of information provided by the fitting guide, strengths and weaknesses, etc.)<br>2. Subjective feedback from the ECP regarding the layout of the fitting guide.<br>3. Surveys of the subjects experience. |
| Study Design | This study is a single arm, non-randomized, open label, non-dispensing clinical trial. The key assessments for this study will be the number of fitting modifications and ECP feedback throughout the fit process while using the Fit Guide. Each ECP will fit at least 3 subjects and no more than 4.<br>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 32 subjects will be enrolled into the study. Approximately 24 are targeted to complete. |
| Study Duration | The study duration is anticipated to be approximately 1 week. |
| Anticipated Study Population | Healthy male and female volunteers with presbyopia will be screened as per criteria outlined below. |
| Eligibility Criteria | Potential subjects must satisfy all of the following criteria to be enrolled in the study:<br>1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form.<br>2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.<br>3. Healthy adult males or females that are at least 40 years of age and no more than 70 years of age.<br>4. The subject must either be wearing a presbyopic contact lens correction (e.g., 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".<br>5. The subject is a current soft spherical or toric contact lens wearer (defined as a minimum of 6 hours of wear per day at least two days of the week for a minimum of 1 month prior to the study).<br>6. The subject's distance spherical equivalent or spherical component (if the eye has -1.00 to -1.50 D of refractive cylinder) of their refraction must be in the range -1.25 D to -3.75 D or +1.25 D to +3.75 D in each eye.<br>7. The subject's refractive cylinder cannot be greater than -1.50D in either eye.<br>8. The subject's refractive cylinder axis must be 90°±30° or 180°±30° in each eye.<br>9. The subject's ADD power must be in the range of +0.75 D to +2.50 D in each eye.<br>10. The subject must have best corrected visual acuity of 20/20-3 or better in each eye.<br>11. The subject must have a wearable pair of spectacles if required for their distance vision.<br><br>Potential subjects who meet any of the following criteria will be excluded from participating in the study:<br>1. Ocular or systemic allergies or disease, or use of medication which might interfere with contact lens wear.<br>2. Pregnancy or lactation.<br>3. Currently diagnosed with diabetes.<br>4. Infectious diseases (e.g. hepatitis, tuberculosis) or an immune-suppressive disease (e.g. HIV).<br>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.<br>6. Entropion, ectropion, extrusions, chalazia, recurrent styes, dry eye, glaucoma, history of recurrent corneal erosions.<br>7. Any previous, or planned, ocular or intraocular surgery (e.g., radial keratotomy, PRK, LASIK, lid procedures, cataract surgery, retinal surgery, etc.).<br>8. A history of amblyopia, strabismus or binocular vision abnormality.<br>9. Any ocular infection or inflammation.<br>10. Any ocular abnormality that may interfere with contact lens wear. |

| | |
|---|---|
| | 11. Use of any ocular medication, with the exception of rewetting drops.<br>12. History of herpetic keratitis.<br>13. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.<br>14. Employee of clinical site (e.g., Investigator, Coordinator, Technician) |
| Disallowed Medications/Interventions | Any systemic medications that may affect contact lens wear and any ocular medications with the exception of rewetting drops. |
| Measurements and Procedures | The key assessments for this study will be the number of fitting modifications and ECP feedback throughout the fit process while using the Fit Guide. |
| 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

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## 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 |
| CTP | Clinical Technical Procedure |
| 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 |

# 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.

Historically ECPs have viewed multifocal lens fitting in general, and toric multifocal lens fitting in particular, as being difficult in terms of the excess time often required to ensure an acceptable level of vision. In addition to the extra time required to fit lenses there is often a low level of overall success. A key aspect of the fitting process is the fitting guide. The ideal fitting guide would be intuitive to the ECP, and by following the recommendations result in a high level of success, with a limited number of lens changes to reduce the time required with each patient. This study aims to evaluate the ECPs impression of the fitting guide for a novel multifocal toric lens and also their success in fitting the lenses.

## 1.1. Name and Descriptions of Investigational Products

Investigational Products: etafilcon A Toric Multifocal Contact Lens
Marketed Products: 1-Day Acuvue® Moist Brand Multifocal Contact Lens
Both products are manufactured in etafilcon-A material and have polyvinylpyrrolidone (PVP) in the packaging solution. The lenses do differ slightly in their mechanical deigns the details of which can be located in the lens Table in section 6.1 of the protocol.

## 1.2. Intended Use of Investigational Products

The toric lens product is indicated to correct presbyopic eyes that have between -1.00 and -1.50D of refractive cylinder. The Control lens is a marketed product and is indicated to be fit on presbyopic eyes that have -0.75D of cylinder or less.

## 1.3. Summary of Findings from Nonclinical Studies

All previous pre-clinical 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-5955 Investigational Brochure. The other product used in this study is the marketed 1-Day Acuvue® Moist Brand Multifocal Contact Lens. Additional information on this lens can be found in the package insert located in the Appendices.

### 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 ammetropia and presbyopia. The lenses have the same stabilization as the marketed 1-DAY ACUVUE® MOIST® for Astigmatism. 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 1-Day Acuvue® Moist Brand Multifocal Contact Lens is a currently marketed product that is also made out of the etafilcon-A material. The contact lenses are available as continuous aspheres providing for the correction of a subjects refractive ammetropia, not including astigmatism, and presbyopia.

The intent of this product is as a daily disposable contact lens that the subject wears while awake. This lens is not intended for 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. Additional details on the 1-Day Acuvue® Moist Brand Multifocal Contact Lens can be found in the package insert.

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

A PubMed search using the terms “multifocal toric contact lens fitting success”, “fitting guides and multifocal contact lenses” and “fitting multifocal contact lenses” resulted in no articles that were relevant to the aims of this study.
The lenses used in this study have been studied in a number of clinical studies ([redacted] and CR-5913). In addition to these studies the lenses are being evaluated in CR-5903 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

Primary Objective(s)
The primary objective of this study is an evaluation of the JJVC Investigational Toric Multifocal and 1-Day Acuvue® Moist Brand Multifocal Contact Lens fitting guides by Eye Care Providers (ECPs).

Secondary Objective(s)

1. Subjective feedback from the ECP on the fitting guide process (i.e. intuitive nature of the fitting steps, adequate amount of information provided by the fitting guide, strengths and weaknesses, etc.)
2. Subjective feedback from the ECP regarding the layout of the fitting guide.
3. Surveys of the subjects experience.

Exploratory Objective(s) Not Applicable

### 2.2. Endpoints

The endpoints will be the number of lenses required for optimization of vision (i.e. ease of fit) and subjective responses from the ECPs regarding the materials/process used for fitting the lenses as well as subjective responses from the subjects.

Primary Endpoint(s)
Number of lenses required to optimize vision.

Secondary Endpoint(s)

1. Subjective feedback from the ECP on the fitting guide process (i.e. intuitive nature of the fitting steps, adequate amount of information provided by the fitting guide, strengths and weaknesses, etc.)
2. Subjective feedback from the ECP regarding the layout of the fitting guide.
3. Surveys of the subjects experience.

Other Observation(s)

### 2.3. Hypotheses

Primary Hypotheses
The maximum number of modification required by the ECP to optimize vision will not exceed one modification in more than 50% of the subjects.

[redacted] **(5)**

Secondary Hypotheses
Not Applicable

Other Hypotheses
Not Applicable

## 3. TARGETED STUDY POPULATION

### 3.1. General Characteristics

Healthy male and female volunteers who are presbyopic will be recruited for the study. The subjects will all be adapted wearers of soft 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. Healthy adult males or females that are at least 40 years of age and no more than 70 years of age.
4. The subject must either be wearing a presbyopic contact lens correction (e.g., 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".
5. The subject is a current soft spherical or toric contact lens wearer (defined as a minimum of 6 hours of wear per day at least two days of the week for a minimum of 1 month prior to the study).
6. The subject's distance spherical equivalent or spherical component (if the eye has -1.00 to -1.50 D of refractive cylinder) of their refraction must be in the range -1.25 D to -3.75 D or +1.25 D to +3.75 D in each eye.
7. The subject's refractive cylinder cannot be greater than -1.50D in either eye.
8. The subject's refractive cylinder axis must be 90°±30° or 180°±30° in each eye.
9. The subject's ADD power must be in the range of +0.75 D to +2.50 D in each eye.
10. The subject must have best corrected visual acuity of $20/20^{-3}$ or better in each eye.
11. The subject must have a wearable pair of spectacles if required for their distance vision.

### 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 (e.g. hepatitis, tuberculosis) or an immune-suppressive disease (e.g. 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 (e.g., 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 (e.g., 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 study is a single arm, non-randomized, open label, bilateral, non-dispensing clinical trial. There is one study visit. Each subject will wear lenses for approximately 30-90 minutes. The key assessments for this study will be the number of fitting modifications and ECP feedback throughout the fit process while using the Fit Guide. Each ECP will fit a maximum of 4 subjects a. At the conclusion of the study subjects will not have access to the investigational lenses. The marketed Moist Multifocal lenses can be obtained from their own

ECP, at the subjects discretion, however no marketed product or contact lens prescriptions will be given to the subject to use outside of this clinical trial.

### 4.2. Study Design Rationale

The primary aim of the study is to obtain ECP feedback on the fitting process of the lenses. With this aim in mind, the study design attempts to create the typical multifocal contact lens fitting scenario encountered in routine clinical practice. The primary purpose of the study is to obtain feedback on the ease of fitting and fitting guide for the multifocal toric lenses and as such there is no need for a Control lens or masking of any of the study personnel.

### 4.3. Enrollment Target and Study Duration

- Approximately 32 subjects will be enrolled in the study with 24 targeted to complete the cohort. An attempt will be made to recruit subjects that have -1.00D to -1.50D of refractive cylinder in at least one eye and no greater than -1.50D in either eye.
- The study will take place at one site and have one study visit per subject. Each ECP will fit a maximum of 4 subjects.

## 5. TEST ARTICLE ALLOCATION AND MASKING

### 5.1. Test Article Allocation

The study is a single-ARM trial.

### 5.2. Masking

The study is open label with no masking. Subjects will be aware of the identity of the investigational product. Investigators and clinical site personnel involved in the data collection will not be masked as to the identity of the investigational product.

### 5.3. Procedures for Maintaining and Breaking Randomization Codes

There is no masking or randomization for this study.

## 6. STUDY INTERVENTION

### 6.1. Identity of Test Articles

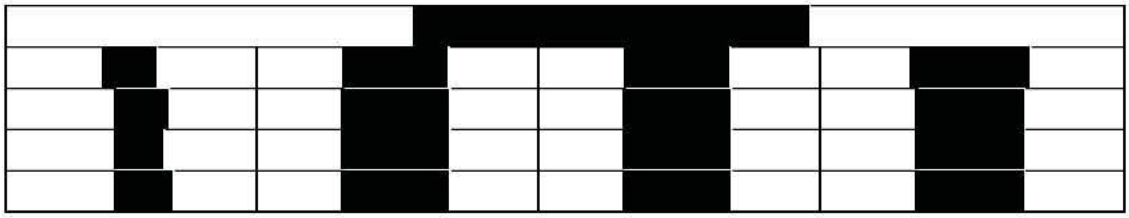
The following contact lenses will be used in this study:

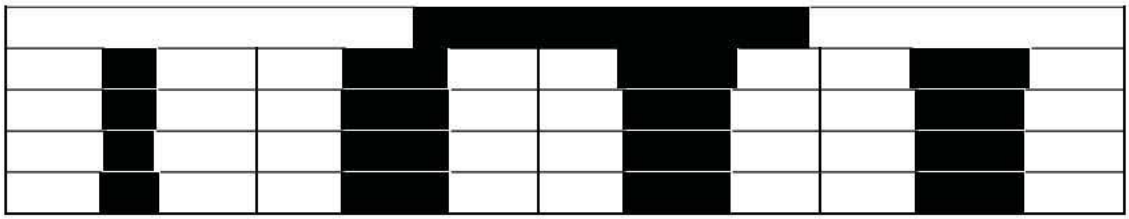
Table 1: Test Articles

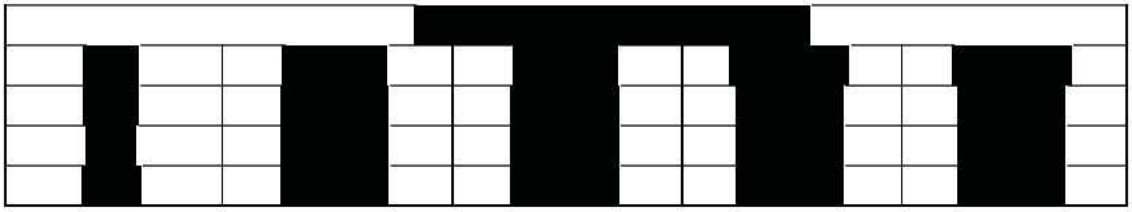
| Name | JJVC Investigational Toric Multifocal Contact Lens for Presbyopia | 1-Day Acuvue® Moist Brand Multifocal Contact Lens |
|---|---|---|
| Manufacturer | Johnson & Johnson® Vision Care, Inc. | Johnson & Johnson® Vision Care, Inc. |
| Compass Protocol(s) and/or Lot Number or Other Identifier | [redacted] Over labeling [redacted] (minus lenses, LOW, MID, HIGH)<br><br>[redacted] and [redacted] Over Labeling [redacted] (plus lenses, LOW, MID, HIGH)<br><br>For the specific clinical build numbers see the tables listed below. | [redacted] Over labeling [redacted] (LOW, MID, HIGH) |
| Lens Material | etafilcon A | etafilcon A |
| Nominal Base Curve @ 22 °C | 8.5 | 8.4 |
| Nominal Diameter @ 22 °C | 14.5 | 14.3 |
| Nominal Distance Powers (D) | -1.00D to -4.00D and +1.00D to +4.00D in 0.25D steps | -1.00D to -4.00D and +1.00D to +4.00D in 0.25D steps |
| Nominal Cylinder Powers (D) and Axes | -1.00D Cylinder<br>Axes for myopic powers: 10°, 20°, 70°, 80°, 90°,100°, 110°, 160°, 170°, 180°<br>Axes for hyperopic powers: 20°, 70°, 90°, 110°, 160°,180° | Not Applicable |
| Nominal ADD Powers (D) | LOW, MID, HIGH | LOW, MID, HIGH |

[redacted] (5)

| | | |
|---|---|---|
| Nominal Water Content | 58% | 58% |
| Oxygen Permeability (Dk) (boundry corrected, non-edge corrected) | 28.0 | 28.0 |
| Modality in Current Study | Daily Wear | Daily Wear |
| Replacement Frequency | Daily Disposable | Daily Disposable |
| Packaging Form (vial, blister, etc.) | Blister | Blister |







[redacted] (5)

Approximately 96 lenses will be used assuming an average of 2 pairs of lenses for each of the 24 subjects. The variation in lens usage will be due to determination whether or not optimization is required.

### 6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 2: Ancillary Supplies

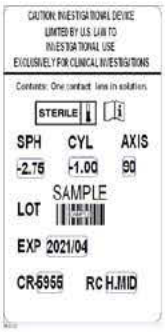
| | Solution |
|---|---|
| Solution Name/Description | Eye-Cept® Rewetting Drops |
| Manufacturer | Non-preserved |
| Preservative | Optics Laboratory |

### 6.3. Administration of Test Articles

Test articles will be dispensed to subject 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 sample study label is shown below:





[redacted] (5)

### 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

Test articles will be disposed of after use and not collected unless associated with an Adverse Event. 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 study 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.
Reference [redacted]: Site Instructions for Test Article Receipt and Test Article Accountability for additional information.

[redacted] (5)

## 7. STUDY EVALUATIONS

### 7.1. Time and Event Schedule

Table 3: Time and Events

| Visit Information | Visit 1 Screening, Baseline, Treatment 1 |
|---|---|
| Time Point | Day 1 |
| Estimated Visit Duration | 5 hours |
| Statement of Informed Consent | X |
| Demographics | X |
| Medical History/Concomitant Medications | X |
| Habitual Contact Lens Information | X |
| Contact Lens History | X |
| Screening Inclusion/Exclusion Criteria | X |
| Subject Reported Ocular Symptoms | X |
| Entrance Snellen Distance Visual Acuity | X |
| Lens Removal | X |
| Subjective Sphero-Cylindrical Refraction | X |
| Near Add Determination | X |
| Ocular Dominance | X |
| Add Refinement | X |
| Near Visual Acuity | X |

| Visit Information | Visit 1 Screening, Baseline, Treatment 1 |
|---|---|
| Time Point | Day 1 |
| Estimated Visit Duration | 5 hours |
| Biomicroscopy | X |
| Baseline Inclusion/Exclusion | X |
| Lens Selection | X |
| ECP Global ID | X |
| Lens Insertion | X |
| Toric Fit (if Applicable) | X |
| Lens Fit Assessment | X |
| 15 Minute Settling | X |
| | |
| ECP Fitting with Fit Guide | X |
| | |
| Modifications (if necessary) | X |
| Post-Fit Questionnaire | X |
| Exit Biomicroscopy | X |
| Final Evaluation | X |
| ECP Interview | X |

### 7.2. Detailed Study Procedures

**VISIT 1**

| 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.<br>**Note**: The subject must be provided a signed copy of this document. | |
| 1.2 | Demographics | Record the subject's date of birth, gender, race | |

[redacted] (5)

| | | | |
|---|---|---|---|
| | | 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 (i.e. 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 | Ocular Symptoms | If the subject reports ocular symptoms with their lenses they will be recorded in the Subject Reported Ocular Symptom Questionnaire | [redacted] |
| 1.8 | Entrance Visual Acuity | Distance and near Snellen visual acuity will be measured for each eye with the subject's correction in place.<br>For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU. | [redacted] |
| 1.9 | Lens Removal (if applicable) | Have the subject remove their habitual lenses and store in an approved storage solution | |
| 1.10 | Subjective Sphero-cylindrical Refraction | Complete optimal binocular balanced spherocylindrical refraction and record the resultant distance visual acuity (OD, OS and OU) to the nearest letter.<br><br>*Note: Best distance visual acuity with sphero-cylindrical refraction must be at least 20/20$^{-3}$ in each eye for the subject to enroll in the study.* | [redacted] |
| 1.11 | Near Add Determination | The near reading addition will be determined using the binocular crossed cylinder technique at 40 cm followed by optimization in a trial | [redacted] |

| | | | |
|---|---|---|---|
| | | frame in step 1.13 below. | |
| 1.12 | Ocular Dominance | Determine the distance ocular dominance with the best distance correction in place using a +1.00 blur test. If the results are equivocal use the sighting dominance test to determine the dominant eye used for the study. | Appendix E |
| 1.13 | Add Refinement | Place the BCC result in the trial frame and refine the near prescription with trial lenses (or flippers) under binocular conditions. | [redacted] |
| 1.14 | Near Visual Acuity | Using the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm. Record the near visual acuity OD, OS and OU at 40 cm. | |
| 1.15 | Biomicroscopy | FDA Slit Lamp Classification Scale will be used to grade the findings and determine eligibility.<br><br>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.<br>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.<br><br>If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled. | [redacted] |
| 1.16 | 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] |
| 1.17 | ECP Global ID | ADD the ECP's global ID. | |
| 1.18 | ECP Lens Selection | The ECP will be provided with the fitting guide and determine the initial study lens selection. The study staff will select the lens pair and power for each eye. Record the test | Appendix F/G Fitting Guides |

| | | | |
|---|---|---|---|
| | | lens parameters (power and lot number). | |
| 1.19 | Lens insertion | Subjects will insert the lenses 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. | |
| 1.20 | Toric Fit Evaluation (if applicable) | The principal or Co-Investigator will evaluate the toric fit and record:<br>• The rotational position to the nearest degree<br>• Lens stability with blink<br>• Lens stability with eye versions<br>• Toric fit acceptable or unacceptable<br>Toric lens fit will be unacceptable if lenses rotated more than 40 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, remove the lenses, perform biomicroscopy and proceed to final evaluation. | [redacted] |
| 1.21 | Lens Fit Assessment | The principal or Co-Investigator will evaluate the general lens fit. Lens fit will be assessed in primary gaze, upgaze & Josephson push up test.<br>An unacceptable lens fit will be any one or more of the following:<br><br>• presence of limbal exposure (appearance of clear cornea) in any gaze<br>• presence of edge lift<br>• Presence of unacceptable movement (excessive or insufficient) in all three movement categories (primary gaze, upgaze, and push-up).<br><br>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] |

[redacted] (5)

| | | | |
|---|---|---|---|
| 1.22 | Lens Settling | Allow the study lenses to continue to settle for a minimum of 15 minutes from the time of lens insertion | |
| 1.23 | ECP Fitting with Fit Guide | The ECP will be provided the fitting guides and assess the vision provided by the lenses and will determine if a lens change is needed. The fitting activities of the ECP will be videotaped. During the fitting of the lenses the ECP may use the slit lamp to evaluate the fit of the lens. . | Appendix F/G Fitting Guides |
| 1.24 | Modifications (if necessary) | If the ECP determines a change in lenses is required they will be allowed two Modifications. If modification is needed complete steps 1.18 to 1.19 for each lens change. | Appendix F/G Fitting Guides |
| 1.25 | Post-Fit Questionnaire | The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire.<br>Subjects will also be shown a product concept of the lens they have just worn and their feedback regarding the concept will be collected. | Appendix A and H |
| 1.26 | Exit Biomicroscopy | The Principal Investigator or Co-Investigator will perform biomicroscopy OD and OS. Slit Lamp Classification Scales will be used to grade the findings.<br>For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading.<br>Corneal Staining Assessment [redacted] will be graded in 1.0 increments. | [redacted] |
| 1.27 | ECP Interview | The ECP will be interviewed regarding their experience fitting the subject using the Fit Guide. | Appendix I |

**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.

| Final Evaluation | | | |
|---|---|---|---|
| Step | Procedure | Details | [redacted] |
| F.1 | Subjective spherocylindrical Refraction | Complete optimal binocular balanced spherocylindrical refraction and record the resultant distance visual acuity (OD, OS and OU) to the nearest letter. | |
| F.2 | Final Exam Form | 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 i.e., 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 | Entrance VA | Record the entrance distance visual acuity (OD, OS and OU) to the nearest letter. | [redacted] |
| U.4 | Subjective Sphero-cylindrical Refraction | Perform bare-eye subjective spherocylindrical refraction with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected distance visual acuity to the nearest letter (OD, OS, OU). | [redacted] |
| U.5 | Slit Lamp Biomicroscopy | FDA Slit Lamp Classification Scale will be used to grade the findings. If no slit lamp finding is noted on the EDC form it is considered as a zero "0" Grade for all observations listed.<br>After the slit lamp examination, at the discretion of the Investigator, rinse the subject's eyes thoroughly with preservative-free saline. | |
| U.6 | Exit Visual Acuity | Record the subject's exit distance visual acuity (OD, OS and OU) to the nearest letter with the subjects wearing the study provided spectacle glasses. | [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 (e.g. 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 (e.g., definite or probable MK) or unexpected device related adverse events, the study will be suspended. Upon review and consultation with IRB, 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 (i.e. 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

[redacted] (5)

- 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 (Refer to [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 (e.g., 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

[redacted] **(5)**

- Non-contact lens related corneal events - e.g. 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 – i.e. the relationship between the Test article, study treatment or study procedures and the adverse event (not related; unlikely related; possibly related; related - 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.
- Unlikely Related – An adverse event for which an alternative explanation is more likely, e.g. concomitant treatment, concomitant disease(s), or the relationship of time suggests that a causal relationship is unlikely.
- Possibly Related – 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, e.g. concomitant treatment, concomitant disease(s), is inconclusive. The relationship in time is reasonable. Therefore, the causal relationship cannot be excluded.
- Related – 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, e.g. concomitant treatment of concomitant disease(s). The relationship in time is very suggestive, e.g. 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 (e.g., 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

None

### 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

There will be one testing site: VRC [redacted] A total of approximately 32 eligible subjects will be enrolled into the study at this site. At least 24 subjects will complete this study. There have been no prior historical studies to evaluate the number of modifications needed in the Test article. As such, the sample size calculation was not based on any power analysis with regard to the primary endpoint.

Using the POWER procedure in SAS 9.4, below is the summary of sample size required based on the different assumptions of the true percentage of subjects with at most one modification.

- Percentage of subjects with at most one modification

| True Percentage (%) | # of subjects needed | Power |
|---|---|---|
| 70 | 56 | 0.913 |

[redacted] (5)

| | | |
|---|---|---|
| 75 | 35 | 0.924 |
| 80 | 23 | 0.928 |

#### 14.3. Analysis Populations

Not Applicable

**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:
Due to the potential low incidence rates of unacceptable lens fitting, summary statistics will be firstly used to evaluate the percentage of the subjects with at most one optimization per-protocol population.
Due to the potential low incidence rates of unacceptable lens fitting, summary statistics will be firstly used to evaluate the percentage of the subjects with at most one optimization per-protocol population.

If applicable, a generalized linear mixed model with a binary distribution and logit link function will be applied to the number of modifications (1=at most one modification; 0 = more than one modification). Age, gender and subjects' add power will be included in the model as fixed effects when appropriate. ECP and subject will be included as random effect.

The proportion of subjects with at most one optimization will be calculated with 95% confidence interval. If the lower limit of the confidence interval is greater than 50%, the statistical superiority will be concluded.

[redacted] (5)

If the incidence rate is too low or there are problems with the convergence of the above model, Agresti methods or Fisher's exact test for binomial proportion will be used to evaluate the confidence intervals of the corresponding endpoints.

### 14.6. Secondary Analysis

This is not applicable.

### 14.7. Other Exploratory Analyses

This is not applicable.

### 14.8. Interim Analysis

This 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:

- 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.

[redacted] (5)

## 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 64$^{th}$ 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.

[redacted] (5)

**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 (e.g., 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 by the Sponsor.

**REFERENCES**


1. ISO 14155:2011: Clinical investigation of medical devices for human subjects – Good clinical practice.

2. Declaration of Helsinki – Ethical principles for Medical Research Involving Human Subjects. Available at: http://www.wma.net/en/30publications/10policies/b3/index.html

# APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

| Study PRO Form Setup For 5955 Version 1 Final | | | | | |
|---|---|---|---|---|---|
| Study [redacted] | Visit [redacted] | Event [redacted] | Setup Order | Type [redacted] | Form [redacted] |
| 5955 | 1 | FIT | 1 | [redacted] | [redacted] |

| PRO Form Specifications for Forms Used in 5955 Version 1 Final | | | | | | | |
|---|---|---|---|---|---|---|---|
| Form [redacted] | Type [redacted] | PRO Domain | PRO Sequence | Item ID# [redacted] | Item Wording | Response Set | Page Number |
| [redacted] | | | | | Please read the following instructions carefully. .• Your opinion is extremely important to us..• Please complete the following questionnaire based on your experience with the contact lenses you were provided. It is important that your answers be based on your own personal opinion as well as your interpretation of the question. Please do not ask others for direction..• Please make every effort to answer each question to the best of your ability and do not leave any question blank. Please be as honest and sincere as possible. If asked to write in an answer, please be as specific as you can. .• Most questions can be answered by checking the appropriate box. Please pay close attention, though, to any additional instructions relating to individual questions throughout the questionnaire. .• Please note that all your answers will be kept strictly confidential. | INSTRUCT | 1 |
| | | | | | Thank you for your participation in the study. | INSTRUCT | 1 |
| | | | | | Considering your experience with the study contact lenses, which statement best describes your overall opinion of these contact lenses? | ExcellenceR | 2 |
| | | | | | Considering your experience with the study contact lenses, which statement best describes your overall satisfaction of these contact lenses? | Satisfaction2 | 3 |
| | | | | | Based on your experience today, how likely are you to purchase this contact lens? | Likelihood2 | 4 |
| | | | | | Please think about your experience today with the study contact lenses. Please indicate how you satisfied you are with the overall contact lens fitting process? | Satisfaction3 | 5 |
| | | | | | Thinking about the process of working with a doctor to select the right contact lens prescription for you with these lenses, if you could improve one thing about this experience today, what would it be? | OpenText | 6 |
| | | | | | Where would you expect to go looking for information about this contact lens? Please select all that apply. | SourceRes | 7 |
| | | | | | If you were to purchase the study contact lenses, for what types of activities would you be most likely to wear them? | OpenText | 8 |
| | | | | | If you were to purchase the study contact lenses, with what frequency would you expect to wear them? | FrequencyATT | 9 |

| PRO Form Specifications for Forms Used in 5955 Version 1 Final | | | | | | | |
|---|---|---|---|---|---|---|---|
| Form [redacted] | Type [redacted] | PRO Domain | PRO Sequence | Item ID# [redacted] | Item Wording | Response Set | Page Number |
| [redacted] | | | | | What are your current vision correction solutions? | CurrentVC2 | 10 |
| | | | | | How did the new lens you tried as a part of this clinical study compare to your current vision correction solutions? | Compare | 11 |
| | | | | | How would this study lens change the vision correction solutions you use today? | OpenText | 12 |
| | | | | | Considering your experience with the study contact lens, how excited are you about this lens being available to purchase? | Excitement | 13 |
| | | | | | How would you rate your overall visual performance with the study contact lens? | ExcellenceR | 14 |
| | | | | | If you were to buy this study lens, what impact do you think it would have on your daily activities? | OpenText | 15 |
| | | | | | If you were to buy this study lens, what impact do you think it would have on your contact lens use? | OpenText | 16 |
| | | | | | As a reference, a typical 6 monthly supply of a daily disposable multifocal contact lens (for both eyes) costs around $350 – $500. | INSTRUCT | 17 |
| | | | | | Please enter a whole dollar amount (without the $) for each question. | INSTRUCT | 17 |
| | | | | | At what price (for a 6 month supply) would you begin to think that this study contact lens is too expensive to consider? | OpenNum | 17 |
| | | | | | At what price (for a 6 month supply) would you begin to think that this study contact lens is so inexpensive that you would question the quality and not consider it? | OpenNum | 17 |
| | | | | | At what price (for a 6 month supply) would you begin to think this study contact lens is getting expensive, but you still might consider it? | OpenNum | 17 |
| | | | | | At what price (for a 6 month supply) would you think that this study contact lens is a bargain – a great buy for the money? | OpenNum | 17 |
| | | | | | PLEASE LET THE INVESTIGATOR OR A STAFF MEMBER KNOW WHEN YOU ARE FINISHED WITH THIS QUESTIONNAIRE. | INSTRUCT | 18 |

| PRO Response Option Specifications for Forms Used in 5955 Version 1 Final | | | | |
|---|---|---|---|---|
| Type [redacted] | Response Set | Selections | Raw Coding | Text Displayed |
| [redacted] | | | 1 | Much better |
| | | | 2 | Somewhat better |
| | | | 3 | About the same |
| | | | 4 | Somewhat worse |
| | | | 5 | Much worse |
| | | | 1 | Toric Contact Lenses |
| | | | 2 | Multifocal Contact Lenses |
| | | | 3 | Monovision |
| | | | 4 | Readers |
| | | | 5 | Progressive Lenses |
| | | | 6 | Other |
| | | | 1 | Excellent |
| | | | 2 | Very Good |
| | | | 3 | Good |
| | | | 4 | Fair |
| | | | 5 | Poor |
| | | | 1 | Very Excited |
| | | | 2 | Excited |
| | | | 3 | Unsure |
| | | | 4 | Unexcited |
| | | | 5 | Very Unexcited |
| | | | 1 | All of the time |
| | | | 2 | Usually |
| | | | 3 | Frequently |
| | | | 4 | Sometimes |
| | | | 5 | Rarely |
| | | | 6 | Never |
| | | | . | |
| | | | 1 | Extremely likely |
| | | | 2 | Very likely |
| | | | 3 | Somewhat likely |
| | | | 4 | Slightly likely |
| | | | 5 | Not at all likely |
| | | | . | |
| | | | . | |

| PRO Response Option Specifications for Forms Used in 5955 Version 1 Final | | | | |
|---|---|---|---|---|
| Type [redacted] | Response Set | Selections | Raw Coding | Text Displayed |
| [redacted] | [redacted] | [redacted] | 1 | Extremely satisfied |
| | | | 2 | Very satisfied |
| | | | 3 | Moderately satisfied |
| | | | 4 | Slightly satisfied |
| | | | 5 | Not at all satisfied |
| | | | 1 | Very Satisfied |
| | | | 2 | Satisfied |
| | | | 3 | Unsure |
| | | | 4 | Dissatisfied |
| | | | 5 | Very Dissatisfied |
| | | | 1 | On a website for a particular brand of contact lenses |
| | | | 2 | On a general healthcare website such as WebMD |
| | | | 3 | In a Magazine |
| | | | 4 | In a Newspaper |
| | | | 5 | On a search engine (ex: Google) |
| | | | 6 | On a Blog |
| | | | 7 | On Social Media Networks (Facebook, Snapchat, etc.) |
| | | | 8 | On YouTube |
| | | | 9 | In an Online Forum |
| | | | 10 | On your Vision Care Insurance Website |
| | | | 11 | Talking with friends family or colleagues |
| | | | 12 | Talking with an eye doctor |
| | | | 13 | Online, but not through an advertisement |
| | | | 14 | Other |

## APPENDIX B: PATIENT INSTRUCTION GUIDE

Not Applicable: Non-Dispensing Study

## APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

1-Day Acuvue® Moist Brand Multifocal Contact Lens

Investigational Product: Not Applicable

**IMPORTANT: Please read carefully and keep this information for future use.**

**This Package Insert and Fitting Guide is intended for the Eye Care Professional, but should be made available to patients upon request.**

**The Eye Care Professional should provide the patient with the appropriate instructions that pertain to the patient's prescribed lenses. Copies are available for download at www.acuvue.com.**

1-DAY ACUVUE® MOIST® BRAND CONTACT LENSES

# 1-DAY ACUVUE® MOIST® Brand Contact Lenses

# 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM

# 1-DAY ACUVUE® MOIST® Brand MULTIFOCAL Contact Lenses

etafilcon A Soft (hydrophilic) Contact Lenses
Visibility Tinted with UV Blocker
for Daily Disposable Wear

℞ Only

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner.

## SYMBOLS KEY

The following symbols may appear on the label or carton:

| SYMBOL | DEFINITION |
|---|---|
|  | Consult Instructions for Use |
|  | Manufactured by or in |
|  | Date of Manufacture |
|  | 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 |
| **MAX ADD** | Near ADD |
| **LOW** | "Low" near ADD |
| **MID** | "Medium" near ADD |
| **HGH** | "High" near ADD |
|  | Quality System Certification Symbol |
|  | UV-Blocking |
|  | Fee Paid for Waste Management |
|  | CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner |
|  | Lens Orientation Correct |
|  | Lens Orientation Incorrect (Lens Inside Out) |
|  | Lens Orientation Correct |
|  | Lens Orientation Incorrect (Lens Inside Out) |

## DESCRIPTION

The 1-DAY ACUVUE® MOIST® Brand Contact Lenses, 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM, and 1-DAY ACUVUE® MOIST® Brand MULTIFOCAL Contact Lenses are soft (hydrophilic) contact lenses available as spherical, toric, and multifocal lenses and include LACREON® Technology.

The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1, 1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate. These lenses are tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling.

A benzotriazole UV absorbing monomer is used to block UV radiation. The UV Blocking averages 97% in the UVB range of 280 nm to 315 nm and 82% in the UVA range of 316 nm to 380 nm.

**Lens Properties:**

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.13
- Refractive Index: 1.40
- Light Transmittance: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 58%
- Oxygen Permeability:

| VALUE | METHOD |
|---|---|
| $21.4 \times 10^{-11}$ ($cm^2$/sec) (ml $O_2$/ml x mm Hg) @ 35°C | Fatt (boundary corrected, edge corrected) |
| $28.0 \times 10^{-11}$ ($cm^2$/sec) (ml $O_2$/ml x mm Hg) @ 35°C | Fatt (boundary corrected, non-edge corrected) |

## AVAILABLE LENS PARAMETERS

The 1-DAY ACUVUE® MOIST® Contact Lenses are hemispherical shells of the following dimensions:

- **Diameter:** 14.2 mm
- **Center Thickness:** 0.084 mm to 0.230 mm (varies with power)
- **Base Curve:** 8.5 mm, 9.0 mm
- **Powers:** -0.50D to -6.00D (in 0.25D increments)
  -6.50D to -12.00D (in 0.50D increments)
  +0.50D to +6.00D (in 0.25D increments)

The 1-DAY ACUVUE® MOIST® Contact Lenses for ASTIGMATISM are hemitoric shells of the following dimensions:

- **Diameter:** 14.5 mm
- **Center Thickness:** 0.090 mm to 0.189 mm (varies with power)
- **Base Curve:** 8.5 mm
- **Powers:** Plano to -6.00D (in 0.25D increments)
  -6.50D to -9.00D (in 0.50D increments)
  Cylinders: -0.75D, -1.25D, -1.75D
  Axis: 10°, 20°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 160°, 170°, 180°

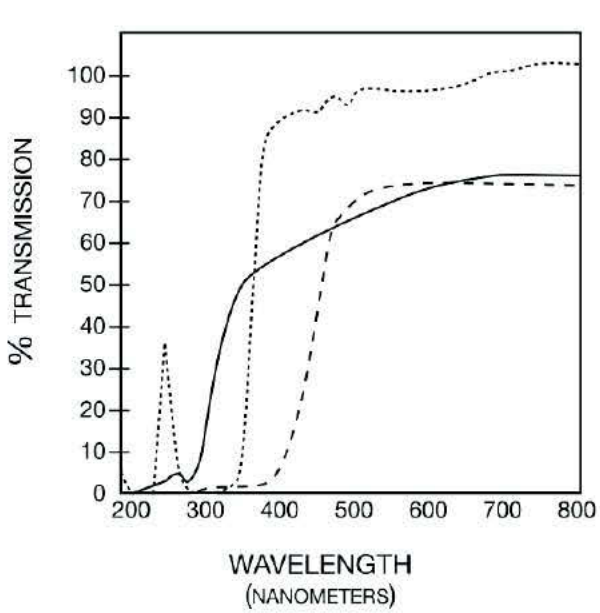
  Plano to -6.00D (in 0.25D increments)
  -6.50D to -9.00D (in 0.50D increments)
  Cylinder: -2.25D
  Axis: 20°, 90°, 160°, 180°

  +0.25D to +4.00D (in 0.25D increments)
  Cylinders: -0.75D, -1.25D, -1.75D
  Axis: 20°, 70°, 90°, 110°, 160°, 180°

The 1-DAY ACUVUE® MOIST® MULTIFOCAL Contact Lenses are hemispherical shells of the following dimensions:

- **Diameter:** 14.3 mm
- **Center Thickness:** 0.084 mm to 0.197 mm (varies with power)
- **Base Curve:** 8.4 mm
- **Powers:** +6.00D to -9.00D (in 0.25D increments)
- **ADD Powers:** +1.25 (LOW), +1.75 (MID), +2.50 (HGH)

## TRANSMITTANCE CURVES




..... 1-DAY ACUVUE® MOIST® Contact Lenses*

——— 24 YR OLD HUMAN CORNEA[1]

- - - - - 25 YR OLD HUMAN CRYSTALLINE LENS[2]

* The data are representative measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-3.00D lens, 0.084 mm center thickness).

**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. The patient should continue to use UV absorbing eyewear as directed.**

[1]Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
[2]Waxler, M., Hitchins, V.M.,Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5

## ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The UV Blocking for these lenses averages 97% in the UVB range of 280 nm to 315 nm and 82% in the UVA range of 316 nm to 380 nm for the entire power range.

**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. The Eye Care Professional should be consulted for more information.**

## INDICATIONS (USES)

The 1-DAY ACUVUE® MOIST® Brand Contact Lenses are indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM are indicated for daily disposable wear for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes who are hyperopic or myopic and may have 0.50D to 3.00D of astigmatism.

The 1-DAY ACUVUE® MOIST® Brand MULTIFOCAL Contact Lenses are indicated for daily disposable wear for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 0.75D or less of astigmatism.

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

## CONTRAINDICATIONS (REASONS NOT TO USE)

**DO NOT USE these lenses if any of the following conditions exist:**

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids
- Severe insufficiency of lacrimal secretion (dry eye)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses

- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e., rewetting drops) that contain chemicals or preservatives (such as mercury or Thimerosal, etc.) to which some people may develop an allergic response
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses
- Any active corneal infection (bacterial, fungal, protozoal, or viral)
- If eyes become red or irritated

## WARNINGS

**Patients should be advised of the following warnings pertaining to contact lens wear:**

**EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE PATIENT EXPERIENCES:**

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes,**
- **Loss of Vision,**
- **Eye Redness, or**
- **Other Eye Problems**

**THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PROFESSIONAL.**

When prescribed for daily wear, patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when lenses are worn overnight, and that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users.[3]

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products are essential for the safe use of these products.

The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care.

[3]New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

## Specific Instructions for Use and Warnings:

- **Water Activity**

  **Instruction for Use**

  Do not expose contact lenses to water while wearing them.

  **WARNING:**

  Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If lenses have been submersed in water when participating in water sports or swimming in pools, hot tubs, lakes, or oceans, the patient should be instructed to discard them and replace them with a new pair. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any activity involving water.

# PRECAUTIONS

## Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.

- Patients who wear these lenses to correct presbyopia using monovision (or modified monovision using 1-DAY ACUVUE® MOIST® MULTIFOCAL Contact Lenses) may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.

- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.

**Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions:**

**Handling Precautions:**

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- **DO NOT** use if the sterile blister package is opened or damaged.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- **DO NOT** touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the "Patient Instruction Guide" for these lenses and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Slide the lens up the side of the bowl until it is free of the container.
- Do not touch the lens with fingernails.

**Lens Wearing Precautions:**

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for a Sticking (Non-Moving) Lens." The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- The patient should be advised to never allow anyone else to wear their lenses. They have been prescribed to fit their eyes and to correct their vision to the degree necessary. Sharing lenses greatly increases the chance of eye infections.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.

**Lens Care Precautions:**

- The patient should be informed that no cleaning or disinfection is needed when lenses are worn for daily disposable wear. Patients should always dispose of lenses when removed and have spare lenses or spectacles available.

### Other Topics to Discuss with Patients:

- Always contact the Eye Care Professional before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

### Who Should Know That the Patient is Wearing Contact Lenses?

- Patients should inform all doctors (Health Care Professionals) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

## ADVERSE REACTIONS

**The patient should be informed that the following problems may occur when wearing contact lenses:**

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, or corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis, and conjunctivitis; some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS. If the problem or discomfort stops, the patient should discard the lens and place a new fresh lens on the eye.

If after inserting the new lens, the problem continues, the patient should be directed to IMMEDIATELY REMOVE THE LENS AND CONTACT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be instructed NOT to use a new lens as self-treatment for the problem.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

## GENERAL FITTING GUIDELINES

### A. Patient Selection

Patients selected to wear these lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear

Patients who do not meet the above criteria should not be provided with contact lenses.

### B. Pre-fitting Examination

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry, and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear these lenses, the Eye Care Professional should proceed to the lens fitting instructions outlined below.

**C. Initial Power Determination**

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00D.

**D. Base Curve Selection (Trial Lens Fitting)**

The following trial lenses should be selected for patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

- 1-DAY ACUVUE® MOIST®: 8.5 mm/14.2 mm
- 1-DAY ACUVUE® MOIST® for ASTIGMATISM: 8.5 mm/14.5 mm
- 1-DAY ACUVUE® MOIST® MULTIFOCAL: 8.4 mm/14.3 mm

The trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

   A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink, and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released.

2. Criteria of a Flat Fitting Lens

   A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the lens is judged to be flat fitting, it should not be dispensed to the patient.

3. Criteria of a Steep Fitting Lens

A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation, and resistance when pushing the lens up digitally with the lower lid. If the lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial trial base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens. The lens should move freely when manipulated digitally with lower lid, and then return to a properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

**E. Final Lens Power (Spherical)**

A spherical over-refraction should be performed to determine the final lens power after the lens fit is judged acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

| **Example 1** | | |
|---|---|---|
| Diagnostic lens: | | -2.00D |
| | Spherical over-refraction: | -0.25D |
| | Final lens power: | -2.25D |

| **Example 2** | | |
|---|---|---|
| Diagnostic lens: | | -2.00D |
| | Spherical over-refraction: | +0.25D |
| | Final lens power: | -1.75D |

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If the fit is acceptable, dispense the lenses and instruct the patient to return in one week for reassessment (see dispensing and follow-up information in **PATIENT MANAGEMENT**).

**All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.**

## TORIC FITTING GUIDELINES

Although most aspects of the fitting procedure are identical for all types of soft contact lenses, including toric lenses, there are some additional steps and/or rules to follow to assure the proper fit of toric lenses.

The only new steps you must follow in prescribing the 1-DAY ACUVUE® MOIST® Contact Lenses for ASTIGMATISM are that you must determine the stability, repeatability, and drift angle of the lens axis so that you can prescribe the correct lens axis for your patient.

### A. How to Determine Lens Cylinder and Axis Orientation for 1-DAY ACUVUE® MOIST® Contact Lenses for ASTIGMATISM

1. Locate the Orientation Marks

   To help determine the proper orientation of the toric lens, you'll find two primary marks approximately 1 mm from the lens edge representing the vertical position on opposite ends of the lens at 6 and 12 o'clock (Fig. 1). Because of the lens' ballasting system, either mark can represent the vertical position – there is no "top" and "bottom" as in a prism-ballasted lens. You don't need to view both marks to assess orientation; simply look for the 6 o'clock mark as you would with a prism-ballasted lens.

    **Figure 1**

   You'll need a slit lamp biomicroscope with a 1 to 2 mm parallelepiped beam to highlight the marks when the lens is fitted to the eye. There are a number of techniques you can use to improve the visibility of the 6 o'clock mark. Using a parallelepiped beam and medium magnification (10x or 15x), slowly pan down the lens, looking just below the direct illumination at the retroilluminated area. Backlighting the mark this way should make it more visible. Sometimes manipulating the lower lid may be necessary to uncover the mark.

2. Observe Lens Rotation and Stability

   Observe the position and stability of the "bottom" mark. It usually stabilizes at the 6 o'clock position. If it does, calculation of the lens power will be straightforward. The 6 o'clock position is not a "must"; however, the absolute requirement is that the axis position be stable and repeatable.

The mark may stabilize somewhat left or right (drift) of the vertical meridian and still enable you to fit a toric lens for that eye, as long as the lens always returns to the same "drift axis" position after settling. The deviation can be compensated for in the final prescription. Your objective is to ensure that whatever position the initial lens assumes near 6 o'clock, this position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens.

**Assessing Rotation**

Imagine the eye as a clock dial and every hour represents a 30° interval. If the orientation mark of the initial lens stabilizes somewhat left or right of the vertical position, the final lens will orient on the eye with the same deviation. You can use an axis reticule in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the "drift angle" of the cylinder axis.

To compensate for this "drift," measure or estimate the "drift," then add or subtract it from the refractive axis to determine the correct cylinder axis. Use the LARS (Left Add, Right Subtract) method to determine which direction to compensate.

**B. Final Lens Power**

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-refraction may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the spectacle cylinder axis, it is not advisable to perform a full spherocylindrical over-refraction because of the difficulty in computing the resultant power. A spherical over-refraction without cylinder refraction may be performed.

If the required cylinder correction falls between two available cylinder powers, it is recommended to prescribe the lower cylinder power lens. See below for instructions on how to determine the final lens power.

**For the Sphere**

If sphere alone or combined sphere and cylinder Rx > 4.00D, compensate for vertex distance.
If sphere alone or combined sphere and cylinder Rx < 4.00D, vertex compensation is not necessary.

**For the Cylinder**
Adjust the axis by the drift angle using the LARS method. Choose a cylinder that is ≤ 0.50D from the refractive cylinder.

**Case Examples**

**Example 1:**
Manifest (spectacle) refraction:
O.D. -2.50 / -1.25 x 180 20/20
O.S. -2.00 / -1.00 x 180 20/20

Choose a diagnostic lens for each eye with axis 180°. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate, based on the patient's initial response to the lens.

Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously.

Here is the Rx prescribed:
O.D. -2.50 / -1.25 x 180
O.S. -2.00 / -0.75 x 180

**Example 2:**
Manifest (spectacle) refraction:
O.D. -3.00 / -1.00 x 90 20/20
O.S. -4.75 / -2.00 x 90 20/20

Choose a diagnostic lens of -3.00 / -0.75 x 90 for the right eye and -4.50 / -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye and allow a minimum of 3 minutes for it to equilibrate.

**Right Eye**
The orientation mark on the right lens rotates left by 10° from the 6 o'clock position and remains stable in this position.
Compensation for this rotation should be done as follows:
Compensate the 10° axis drift by adding it to the manifest refraction axis.

Here is the Rx prescribed:
O.D. -3.00 / -0.75 x 100

**Left Eye**
The orientation mark on the left lens rotates right by 10° from the 6 o'clock position and remains stable in this position.

Since the manifest refraction called for a power of -4.75D, compensating for vertex distance the sphere is reduced by 0.25D to -4.50D. The cylinder power will be -1.75D. Compensate for the 10° axis drift to the right by subtracting it from the manifest refraction axis.

Here is the Rx prescribed:
O.S. -4.50 / -1.75 x 80

**All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.**

## MULTIFOCAL FITTING GUIDELINES

### A. Presbyopic Needs Assessment & Patient Education

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e., reading a menu in a dim restaurant, driving at night in rainy/foggy conditions, etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the 1-DAY ACUVUE® MOIST® MULTIFOCAL Contact Lenses. Wearing the 1-DAY ACUVUE® MOIST® MULTIFOCAL Contact Lenses may not be optimal for activities such as:

1. Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. Driving automobiles (e.g., driving at night). Patients who cannot meet their state driver's license requirements with the 1-DAY ACUVUE® MOIST® MULTIFOCAL Contact Lenses should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

1-DAY ACUVUE® MOIST® MULTIFOCAL Contact Lenses are not recommended for patients who have -1.00D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise.

The 1-DAY ACUVUE® MOIST® MULTIFOCAL Contact Lenses are available in the following ADD powers:

- Lens “LOW” = “low” near ADD lens (Max ADD +1.25)
- Lens “MID” = “medium” near ADD lens (Max ADD +1.75)
- Lens “HGH” = “high” near ADD lens (Max ADD +2.50)

**B. Initial Power Determination**

A spectacle refraction should be performed to establish the patient’s baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00D. Determine the spherical equivalent distance prescription for a multifocal patient. Determine the eye dominance using one of the methods below:

Method 1: Determine which eye is the “sighting eye.” Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2: Determine which eye does not accept added plus power. Place a +1.00D hand-held trial lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes while the patient is viewing the distance visual acuity chart. The eye with the plus over it that the patient notices the greatest reduction in vision is determined to be the dominant eye.

**C. Select the Initial Trial Lens**

1. For each eye, select the trial lens distance power that is closest to the patient’s distance spherical equivalent. Remember to compensate for vertex distance if the refraction is greater than ±4.00D.
2. Select the near power of the lens based on the patients ADD range as follows:
   - ADD: +0.75 to +1.25 use a “LOW” near ADD lens on each eye
   - ADD: +1.50 to +1.75 use a “MID” near ADD lens on each eye
   - ADD: +2.00 to +2.50 use a “MID” near ADD on the dominant eye and a “HGH” near ADD lens on the non-dominant eye
3. Allow the lenses to settle for a minimum of 10 minutes.
4. Assess distance and near vision binocularly and monocularly.
5. Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate, and near.

6. Make adjustments in power as necessary based on the distance over-refraction. The use of hand held trial lenses is recommended. Check the impact on distance and near vision.
7. If vision is still unacceptable, make adjustments in power as necessary (see "Multifocal Troubleshooting" below). If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

**D. Multifocal Troubleshooting**

**Unacceptable Near Vision:**
If it has been determined that no change is required based on the over-refraction, then add +0.25D to the spherical power of the non-dominant eye.

**Unacceptable Distance Vision:**
If it has been determined that no change is required based on the over-refraction, then make the changes as listed below:

- If the patient is wearing two "LOW" ADD lenses, change the dominant eye to a 1-DAY ACUVUE® MOIST® sphere lens with a power equal to the spherical equivalent distance prescription.
- If the patient is wearing two "MID" ADD lenses, change the ADD power in the dominant eye to the "LOW" ADD power.
- If the patient is wearing a "MID" ADD lens in the dominant eye and a "HGH" ADD lens in the non-dominant eye, change the non-dominant eye to a "MID" ADD lens and add +0.25D to the distance power.

**E. Adaptation**

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

**All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.**

## MONOVISION FITTING GUIDELINES

**A. Patient Selection**

**Monovision Needs Assessment**

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient with significant astigmatism (greater than 1.00D) in one eye may not be a good candidate for monovision correction with these lenses.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision correction. Monovision contact lens wear may not be optimal for activities such as:

1. Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. Driving automobiles (e.g., driving at night). Patients who cannot meet their state driver's license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

**Patient Education**

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with spectacles (multifocal, bifocal, trifocal, readers, or progressives). Each patient should understand that monovision, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Therefore, caution should be exercised. During the

fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision, and straight ahead and upward gaze that monovision contact lenses provide.

**B. Eye Selection**

Generally, the non-dominant eye is corrected for near vision. The following two methods for eye dominance can be used.

1. **Ocular Preference Determination Methods**

   Method 1: Determine which eye is the "sighting eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

   Method 2: Determine which eye will accept the added power with the least reduction in vision. Place a hand-held trial lens equal to the spectacle near ADD in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near ADD lens over the right or left eye.

Other methods include the "Refractive Error Method" and the "Visual Demands Method."

2. **Refractive Error Method**

   For anisometropic correction, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

3. **Visual Demands Method**

   Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, correct the eye on that side for near.

   Example:

   A secretary who places copy to the left side of the desk will function best with the near lens on the left eye.

**C. Special Fitting Characteristics**

1. **Unilateral Vision Correction Requirement**

   There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens, whereas a bilateral myope would require corrective lenses on both eyes.

Examples:

A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without correction.

A presbyopic patient requiring a +1.50D ADD who is –2.50D myopic in the right eye and –1.50D myopic in the left eye may have the right eye corrected for distance and the left eye uncorrected for near.

**2. Near ADD Determination**

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

**3. Trial Lens Fitting**

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the **GENERAL FITTING GUIDELINES** for base curve selection described in this guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine the distance correction and the near correction. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Allow the lenses to settle for about 20 minutes with the correct power lenses in place. Walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tests are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

**4. Adaptation**

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

**5. Other Suggestions**

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- Have supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet their state driver's license requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Monovision fitting success can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of clear near vision, and straight ahead and upward gaze with monovision.

The decision to fit a patient with monovision correction is most appropriately left to the Eye Care Professional in conjunction with the patient after carefully considering the patient's needs.

**All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.**

## PATIENT MANAGEMENT

**Dispensing Visit**

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with povidone. To remove the lens from the container, peel back the foil seal, 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.

- Evaluate the physical fit and visual acuity of the lens on each eye.
- Teach the patient how to apply and remove his or her lenses.
- Explain daily disposable lens wear and schedule a follow-up examination.
- **Provide the patient with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download at www.acuvue.com.**

  **REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULES.**

**Follow-Up Examinations**

Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule, daily disposable modality, and proper lens handling procedures.

**A. Recommended Follow-up Examination Schedule (complications and specific problems should be managed on an individual patient basis):**

1. One week from the initial lens dispensing to patient
2. One month post-dispensing
3. Every three to six months thereafter

**NOTE:** Preferably, at the follow-up visits, lenses should be worn for at least six hours.

**B. Recommended Procedures for Follow-Up Visits:**

1. Solicit and record patient's symptoms, if any.
2. Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.
3. Perform an over-refraction at distance and near to check for residual refractive error.
4. With the biomicroscope, judge the lens fitting characteristics (as described in the **GENERAL FITTING GUIDELINES**) and evaluate the lens surface for deposits and damage.
5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein (unless contraindicated).
    - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
    - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
    - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

**If any observations are abnormal, use professional judgment to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.**

## WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Professional. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Maximum wearing time should be determined by the Eye Care Professional based upon the patient's physiological eye condition, because individual response to contact lenses varies.

The maximum suggested wearing time for these lenses is:

| Day | Hours |
|---|---|
| 1 | 6-8 |
| 2 | 8-10 |
| 3 | 10-12 |
| 4 | 12-14 |
| 5 and after | all waking hours |

## REPLACEMENT SCHEDULE

These lenses are indicated for daily disposable wear and should be discarded upon removal.

When disposed of after a single daily use, these lenses may reduce the risk of developing giant papillary conjunctivitis.[4]

When worn as a daily disposable lens, these lenses may provide improved comfort for many patients who experience mild discomfort and itching associated with allergies during contact lens wear, compared to lenses replaced at intervals of greater than 2 weeks.

Clinical Research has shown that when worn on a daily disposable basis, these lenses may provide improved comfort for 2 out of 3 patients who reported suffering from discomfort associated with allergies during contact lens wear.

[4] The CLAO Journal, July 1999, Volume 25, Number 3

## LENS CARE DIRECTIONS

When lenses are prescribed for daily disposable wear, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions for daily disposable lens wear at the time they are dispensed.

The Eye Care Professional should review with patients that no cleaning or disinfection is needed with disposable lenses. Patients should always dispose of lenses when they are removed and have spare lenses or spectacles available.

**Basic Instructions**

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Eye Care Professionals may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

**Care for a Sticking (Non-Moving) Lens**

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should **immediately** consult the Eye Care Professional.

## EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

## HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with povidone. The plastic package is marked with the following:

- **1-DAY ACUVUE® MOIST®:** base curve, power, diameter, lot number, and expiration date
- **1-DAY ACUVUE® MOIST® for ASTIGMATISM:** base curve, power, diameter, cylinder, axis, lot number, and expiration date
- **1-DAY ACUVUE® MOIST® MULTIFOCAL:** base curve, power, diameter, ADD, lot number, and expiration date

## REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing these lenses or experienced with these lenses should be reported to:

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-800-843-2020
www.acuvue.com



Printed in USA
Revision date: 09/14
Revision number: M-09-14-00

## APPENDIX D: PRESBYOPIC SYMPTOMS

### 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 (i.e., 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: OCULAR DOMINANCE

**OCULAR DOMNANCE TEST**

### +1.00 D LENS TEST

Step 1 Place the subjects best sphero-cylindrical distance refraction in a trial frame.

Step 2 Have the subject view a BVA line of letters.

Step 3 With both eyes open alternate a +1.00 D trial lens between the right and left eye and ask the subject to indicate over which eye does the lens cause the line of letters to appear more blurred. The eye that the greatest blur is reported is the distance dominant eye. If the subject indicates that the amount of blur is about the same between the two eyes then record as neither eye dominant.

### SIGHTING OCULAR DOMINANCE

Step 1 Ask the subject to extend both arms out and use his/her hands to form a triangle. The subject will be asked to keep both eyes open, and look through the triangle at a small object on the wall (e.g., a light switch or doorknob).

Step 2 Occlude the subject's left eye, then right eye. While alternating the occluder from the subject's eyes, ask the subject when they see the object.

If the subject sees the object when the left eye is covered, the subject is *right eye* dominant.

If the subject sees the object when the right eye is covered, the subject is *left eye* dominant.

If the subject sees the object with both eyes, the opening between the hands may be too large. Therefore, ask the subject to make a smaller opening and repeat the procedure.

## APPENDIX F: FITTING GUIDE OPTION 1

## APPENDIX G: FITTING GUIDE OPTION 2

[redacted] (5)

## APPENDIX H: SUBJECT PRODUCT CONCEPT

## APPENDIX I: ECP INTERVIEW DISCUSSION MATERIALS

## APPENDIX J: CLINICAL TECHNICAL PROCEDURES (CTP)

- [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] (5)

## [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] (5)

## [redacted]: BIOMICROSCOPY SCALE

## [redacted]: DISTANCE AND NEAR VISUAL ACUITY EVALUATION

[redacted] (5)

## [redacted]: TORIC FIT EVALUATION

**PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE**

Protocol Number and Title: CR-5955 Evaluation of the JJVC Investigational Toric Multifocal Contact Lens Fitting Guide Phase II
Version and Date: v2.0, Amendment 1.0 April 17, 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

[redacted] (5)