Clinical Study Protocol
Johnson & Johnson Vision Care, Inc.

Evaluation of Lens Rotation in Habitual Wearers of Toric, Soft Contact Lenses

Protocol CR-6576[redacted]

Version: 1.0

Date: 03 October 2024

Test Articles:
Marketed ACUVUE® OASYS 1-Day for Astigmatism contact lenses (Test Lens) from JJVCI and Dailies® Total1 for Astigmatism contact lenses (Control Lens) from Alcon Inc.

Commercially Available Product Lots: ACUVUE® OASYS 1-Day for Astigmatism contact lenses from JJVCI and Dailies® Total1 for Astigmatism contact lenses from Alcon Inc.

Keywords: Astigmatism, senofilcon A, ACUVUE® OASYS 1-Day for Astigmatism, Dailies® Total1 for Astigmatism contact lenses from Alcon, delefilcon A, daily wear, daily disposable, non-dispensing, Visual Analogue Scores, logMAR visual acuity, rotation performance.

Statement of Compliance to protocol, GCP and applicable regulatory guidelines:

This clinical trial will be conducted in compliance with ISO 14155:2020[1], Declaration of Helsinki[2], United States (US) Code of Federal Regulations (CFR)[3], and International Council for Harmonization Good Clinical Practice E6(R2) (ICH GCP)[4].

Confidentiality Statement:

[redacted]

[redacted]

[redacted]

[redacted]

PROTOCOL TITLE, NUMBER, VERSION AND DATE

Title: Evaluation of Lens Rotation in Habitual Wearers of Toric, Soft Contact Lenses
Protocol Number: CR-6576
Version: 1.0
Date: 03 October 2024

SPONSOR NAME AND ADDRESS

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

MEDICAL MONITOR

[redacted]

The Medical Monitor must be notified by the clinical institution/site by e-mail 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 the assigned clinical research associate.

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

AUTHORIZED SIGNATURES

The signatures below constitute the approval of this protocol and the attachments and provide 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, ISO 14155:2020,[1] Declaration of Helsinki[2] , and the United States (US) Code of Federal Regulations (CFR)[3], and International Council for Harmonization Good Clinical Practice E6(R2) (ICH GCP)[4]

Author & Study Responsible Clinician	*See Electronic Signature Report* [redacted]	DATE
Clinical Operations Manager	*See Electronic Signature Report* [redacted]	DATE
Co-Author	[redacted]	DATE
Biostatistician	*See Electronic Signature Report* [redacted]	DATE
Data Management	*See Electronic Signature Report* [redacted]	DATE
Medical Safety Officer	*See Electronic Signature Report* [redacted]	DATE
Medical Monitor	*See Electronic Signature Report* [redacted]	DATE
Platform Lead/Project Lead/Director	*See Electronic Signature Report* [redacted]	DATE

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SYNOPSIS

Protocol Title	Evaluation of Lens Rotation in Habitual Wearers of Toric, Soft Contact Lenses
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Clinical trial phase: Feasibility Design control phase: Development phase, phase 0.
Trial Registration	This study will be registered on ClinicalTrials.gov by the sponsor.
Test Article(s)	Investigational Products: None Approved Products (locally sourced by research site): 1. ACUVUE® OASYS 1-Day for Astigmatism (AO1DfA) contact lenses for Johnson and Johnson Vision Inc. (Test Lens) 2. Dailies® Total1 for Astigmatism (DT1fA) contact lenses from Alcon Inc. (Control Lens)
Wear and Replacement Schedules	Wear Schedule: daily wear Replacement Schedule: daily disposable
Objectives	**Primary Objective:** The primary objective of this study is to measure the monocular distance (6m) logMAR visual acuity with each study lens (Test lens and Control lens) after lens fitting. **Other (Exploratory) Objectives:** The exploratory objectives of this study include changes in lens orientation after settling and over time with an automated lens tracking system; VAS scores after lens fitting for vision, comfort and handling; and lens orientation at 1, 3, and 15-minutes following insertion. Adverse events and slit lamp findings will also be monitored and collected.
Study Endpoints	**Primary Efficacy Endpoint**: 1. Distance Visual Acuity **Other (Exploratory) Efficacy Endpoints:** 1. Lens orientation measured over time with an automated lens tracking system following intentional misalignment 2. Lens orientation recorded with an automated lens tracking system following eye movements 3. Settling Time following intentional misalignment 4. Toric Lens orientation at 1-, 3-, and 15-minutes following insertion 5. Subjective Vision, Comfort and Handling Scores approximately 15-minutes after lens insertion **Other Safety Endpoints:** 1. Adverse Events (AEs) 2. Slit Lamp Findings (SLFs)

Study Design	This will be a single site, 2-visit, randomized, controlled, single-masked, non-dispensing, bilateral wear, 2×2 cross-over study. Each subject will be randomly assigned to one of two wear sequences. There will be a washout period of 1-10 days in between the visits. There will be a total of 2 visits: Visit 1: Screening, baseline evaluation and lens fit #1 Visit 2: Continuance, lens fit #2, Exit evaluation 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	This study will have an enrollment target of approximately 7 subjects, with a target of at least 5 to complete. This is a crossover study, and all subjects will be randomized to one of 2 unique sequences of lens wear.
Study Duration	Total study duration including the enrollment period is anticipated to be approximately 6 weeks. The expected duration of participation of the subject will be approximately 1 week.
Anticipated Study Population	Subjects will be habitual toric, soft contact lens wearers with bilateral astigmatism who are between 18 and 39 years of age (inclusive).
Eligibility Criteria - Inclusion	Potential subjects must satisfy of all the following criteria to be enrolled in the study. Inclusion Criteria following Screening The subject must: 1. Read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form. 2. Appear able and willing to adhere to the instructions set forth in this clinical protocol. 3. Be between 18 and 39 years of age (inclusive) at the time of screening. 4. Habitually wear soft, toric contact lenses in both eyes in a daily or daily disposable wear modality (i.e. not extended wear modality). Habitual wearer is defined as a minimum of 6 hours per day, for a minimum of 2 days per week during the past 30 days. 5. Possess a wearable pair of spectacles that provide correction for distance vision (if applicable). Inclusion Criteria at Baseline Evaluation The subject must: 6. Have the spherical component of their vertex-corrected distance refraction within the range +4.00 to -6.00 DS (inclusive) in both eyes. 7. Have the magnitude of the negative cylindrical component of their vertex-corrected distance refraction between 0.75 DC and 2.50 DC in both eyes. 8. Have best corrected monocular distance logMAR visual acuity of 0.2 or better in each eye.

Eligibility Criteria – Exclusion	Potential subjects who meet any of the following criteria will be excluded from participating in the study. Exclusion Criteria following Screening The subject must not: 1. Be currently pregnant or lactating. 2. Be diabetic. 3. Be currently using any ocular medications or have any ocular infection of any type. 4. By self-report, have any ocular or systemic disease, allergies, infection, or use of medication that might contraindicate or interfere with contact lens wear, or otherwise compromise study endpoints, including infectious disease (e.g., hepatitis, tuberculosis), contagious immunosuppressive disease (e.g., Human Immunodeficiency Virus [HIV]), autoimmune disease (e.g. rheumatoid arthritis, Sjögren's syndrome), or history of serious mental illness or seizures. See section 9.1 for additional details regarding excluded systemic medications. 5. Have habitually worn rigid gas permeable (RGP) lenses, orthokeratology lenses, or hybrid lenses (e.g. SynergEyes, SoftPerm) within the past 6 months. 6. Be currently wearing monovision or multifocal contact lenses. 7. Be currently wearing lenses in an extended wear modality. 8. Be currently wearing or have had worn Acuvue® Oasys 1-Day for Astigmatism, or Dailies® Total1 for Astigmatism lenses during the last 3 months. 9. Have a history of strabismus or amblyopia. 10. Be an employee (e.g., Investigator, Coordinator, Technician) or immediate family member of an employee (including partner, child, parent, grandparent, grandchild or sibling of the employee or their spouse) of the clinical site. 11. Have participated in a contact lens or lens care product clinical trial within 7 days prior to study enrollment. Exclusion Criteria at Baseline Evaluation The subject must not: 12. Have clinically significant (grade 3 or higher on the Efron grading scale) slit lamp findings (e.g., corneal edema, neovascularization or staining, tarsal abnormalities or bulbar injection) or other corneal or ocular disease or abnormalities that contraindicate contact lens wear or may otherwise compromise study endpoints (including entropion, ectropion, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, moderate or above corneal distortion, herpetic keratitis). 13. Have fluctuations in vision due to clinically significant dry eye or other ocular conditions. 14. Have had or have planned (within the study period) any ocular or intraocular surgery (e.g., radial keratotomy, PRK, LASIK, iridotomy, retinal laser photocoagulation, etc.).
Disallowed Medications/Interventions	Subjects will not be eligible to enroll if they are taking any ocular medications, or any systemic medications that would normally contraindicate contact lens wear or may otherwise compromise study endpoints. See section 9.1 for details regarding disallowed systemic medications.

Measurements and Procedures	The key procedure associated with the primary endpoint for this study will be the evaluation of monocular logMAR visual acuity. Other measurements and procedures related to observational endpoints will include: - Lens orientation and stability in different time points following insertion - Lens rotation over time following intentional misalignment measured with an automated lens tracking instrument - Lens orientation following eye movements in 8 directions of gaze - Completion of the VAS questionnaires at fitting
Microbiology or Other Laboratory Testing	Not applicable for this study.
Study Termination	The occurrence of an Unanticipated Adverse Device Effect (UADE), Unanticipated Serious Adverse Device Effect (USADE), or Serious Adverse Event (SAE) for which a causal relationship to a test article cannot be ruled out, may result in stopping further dispensing of the test article. 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	Non-preserved saline (locally sourced by research site)
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.

COMMONLY USED ABBREVIATIONS, ACRONYMS AND DEFINITIONS OF TERMS

ADE	Adverse Device Effect
ADHD	Attention Deficit Hyperactivity Disorder
AE	Adverse Event/Adverse Experience
AO1DfA	ACUVUE OASYS® 1-DAY with HydraLuxe™ TECHNOLOGY for ASTIGMATISM
BSCVA	Best Spectacle Corrected Visual Acuity
CFR	Code of Federal Regulations
CI	Confidence Interval
CLUE	Contact Lens User Experience
COM	Clinical Operations Manager
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
[redacted]	[redacted]
D	Diopter
DMC	Data Monitoring Committee
DT1fA	Dailies® Total1 for Astigmatism
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
ESD	Eyelid Stabilized Design
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HEV	High Energy Visible
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HLHC	High-Luminance, High-Contrast
IB	Investigator's Brochure
ICH	The International Council for Harmonization
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intention-to-Treat
JJVC	Johnson & Johnson Vision Care, Inc.
LASIK	Laser-Assisted in Situ Keratomileusis
LogMAR	Logarithm of Minimal Angle of Resolution
OD	Right Eye
OS	Left Eye
OU	Both Eyes
PIG	Patient Instruction Guide
PQC	Product Quality Complaint
PRK	Photorefractive Keratectomy
PRO	Patient Reported Outcome
QA	Quality Assurance
SAE	Serious Adverse Event/Serious Adverse Experience
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SLF	Slit Lamp Findings
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
UV	Ultraviolet
VA	Visual Acuity
VAS	Visual Analogue Scale

1. INTRODUCTION AND BACKGROUND

Johnson and Johnson Vision currently market ACUVUE® OASYS 1-Day for Astigmatism daily disposable contact lenses which uses Blink Stabilized Technology to achieve rotational stability, while other manufacturers use other prism or peri-ballast mechanisms for rotational stability.

This study is designed to assess monocular distance visual acuity with the two marketed study lenses. The study will also evaluate the rotational performance of the two marketed lenses using an automated lens tracking instrument and custom software developed by Eurolens Research, at the University of Manchester.

[redacted]

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

Primary Objective

The primary objective of this study is to measure the monocular distance (6m) logMAR visual acuity with each study lens (Test lens and Control lens) after lens fitting.

Other (Exploratory) Objectives

The exploratory objectives of this study include lens orientation and stability after settling, changes in lens orientation over time following intentional misalignment, changes in lens orientation following eye movements in 8 directions of gaze, VAS scores at fitting (comfort, vision, and handling), and lens orientation at 1- and 3-minutes following insertion. Adverse events will also be monitored and collected.

2.2. Endpoints

2.2.1. Efficacy Endpoints

Primary Efficacy Endpoint

1. Distance (6m) Visual Acuity

The primary endpoint for this study will be distance visual acuity measured monocularly at 6 meters after lens fitting under high-luminance high contrast (HLHC) lighting conditions using the Eurolens computerized logMAR VA chart. The logMAR VA score is a continuous endpoint.

Other (Exploratory) Efficacy Endpoints

1. Lens orientation measured over time with an automated lens tracking system following intentional misalignment
   Each study lens will be rotated in the temporal direction from its original position to its worst case orientation (90° from its settled position for the AO1DfA lens which has a bidirectional stabilization design, and 180° from its settled position for the DT1fA lens which has a unidirectional stabilization design), followed by video capture of the lens orientation over a 5-minute period. Lens orientation data (rotation error magnitude and direction relative to the 6 o'clock position, and rotation error magnitude and direction relative to original settled position) will be calculated at 5-second increments through the measurement period. Rotation error magnitude will be recorded in degrees (0 to 180), and rotation error direction will be recorded as base temporal or nasal. For the DT1fA lens type, recovery from 90° misalignment will also be determined from the timepoint that it reaches this position during the recovery from 180° of misalignment.

2. Lens orientation recorded with an automated lens tracking system following eye movements
   Lens settled orientation (rotation error magnitude and direction relative to the 6 o'clock position) in primary gaze will be measured. Lens orientation will then be measured again after the subject has been asked to perform an eye movement in each of the eight cardinal directions of gaze. The difference in orientation (magnitude and direction) from before eye movement to after eye movement will be determined.

3. Settling Time following intentional misalignment
   The time (in seconds) required for the study lenses to settle (defined as returning to within 5 degrees of initial settled position) after intentional misalignment will be recorded for each eye and lens during the assessment of the lens orientation recorded with an automated lens tracking system (Other efficacy endpoint 1). Settling time is a continuous endpoint.

4. Toric lens orientation
   Toric lens orientation (scribe mark position relative to 6 o'clock) will be assessed for each eye at 1, 3 and at least 15 minutes after lens insertion at the fitting visit. The endpoint is the distribution (counts, percentages) of eyes for the toric orientation (in degrees). Toric lens stability with blink at least 15 minutes after lens insertion will also be recorded. See [redacted] in Appendix D for details regarding the collection of lens orientation.

5. Subjective Vision, Comfort and Handling Scores
   Vision, comfort and handling will be assessed monocularly approximately 15-minutes after lens insertion using individual questionnaire items with a Visual Analogue Scale (VAS). The VAS scale for each item is continuous set where scores range from 0 (represent worst imaginable vision, comfort, or extreme difficulty in lens handling) to 100 (represent best imaginable vision, comfort, or easiest to handle). Vision, comfort, and handling scores are continuous endpoints. See appendix A for the details of the study questionnaire.

2.2.2. Safety Endpoints

Primary Safety Endpoint
Not applicable

Secondary Safety Endpoint
Not applicable

Other Safety Endpoint

1. Adverse events (AEs) - including ocular and non-ocular. Details for AEs will be provided through listings.
2. Slit lamp findings (SLFs) – the SLF grades determined using the Efron Grading Scale will be summarized descriptively.

2.3. Hypotheses

Not applicable, no statistical hypothesis testing will be performed for any endpoints in this study.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

The target population for this study will be healthy adult soft, toric contact lens wearers between 18 and 39 years of age with binocular astigmatism.

3.2. Inclusion Criteria

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

Inclusion Criteria following Screening
The subject must:

1. Read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form.
2. Appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. Be between 18 and 39 years of age (inclusive) at the time of screening.
4. Habitually wear soft, toric contact lenses in both eyes in a daily or daily disposable wear modality (i.e. not extended wear modality). Habitual wearer is defined as a minimum of 6 hours per day, for a minimum of 2 days per week during the past 30 days.
5. Possess a wearable pair of spectacles that provide correction for distance vision (if applicable).

Inclusion Criteria at Baseline Evaluation
The subject must:

6. Have the spherical component of their vertex-corrected distance refraction within the range +4.00 to -6.00 DS (inclusive) in both eyes.
7. Have the magnitude of the cylindrical component of their vertex-corrected distance refraction between 0.75 DC and 2.50 DC in both eyes.
8. Have best corrected monocular distance visual acuity of 0.2 or better in each eye.

3.3. Exclusion Criteria

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

Exclusion Criteria following Screening
The subject must not:

1. Be currently pregnant or lactating.
2. Be diabetic.
3. Be currently using any ocular medications or have any ocular infection of any type.
4. By self-report, have any ocular or systemic disease, allergies, infection, or use of medication that might contraindicate or interfere with contact lens wear, or otherwise compromise study endpoints, including infectious disease (e.g., hepatitis, tuberculosis), contagious immunosuppressive disease

(e.g., Human Immunodeficiency Virus [HIV]), autoimmune disease (e.g. rheumatoid arthritis, Sjögren's syndrome), or history of serious mental illness or seizures. See section 9.1 for additional details regarding excluded systemic medications.

5. Have habitually worn rigid gas permeable (RGP) lenses, orthokeratology lenses, or hybrid lenses (e.g. SynergEyes, SoftPerm) within the past 6 months.
6. Be currently wearing monovision or multifocal contact lenses.
7. Be currently wearing lenses in an extended wear modality.
8. Be currently wearing or have had worn Acuvue® Oasys 1-Day for Astigmatism, or Dailies® Total1 for Astigmatism lenses during the last 3 months.
9. Have a history of strabismus or amblyopia.
10. Be an employee (e.g., Investigator, Coordinator, Technician) or immediate family member of an employee (including partner, child, parent, grandparent, grandchild or sibling of the employee or their spouse) of the clinical site.
11. Have participated in a contact lens or lens care product clinical trial within 7 days prior to study enrollment.

Exclusion Criteria at Baseline Evaluation
The subject must not:

12. Have clinically significant (grade 3 or higher on the Efron grading scale) slit lamp findings (e.g., corneal edema, neovascularization or staining, tarsal abnormalities or bulbar injection) or other corneal or ocular disease or abnormalities that contraindicate contact lens wear or may otherwise compromise study endpoints (including entropion, ectropion, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, aphakia, moderate or above corneal distortion, herpetic keratitis).
13. Have fluctuations in vision due to clinically significant dry eye or other ocular conditions.
14. Have had or have planned (within the study period) any ocular or intraocular surgery (e.g., radial keratotomy, PRK, LASIK, iridotomy, retinal laser photocoagulation, etc.).

[redacted]

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This will be a single site, 2-visit, randomized, controlled, single-masked, non-dispensing, bilateral wear, 2×2 cross-over study. Each subject will be randomly assigned to one of two wear sequences (AO1DfA followed by DT1fA or DT1fA followed by AO1DfA), with a 1-to-10 day(s) washout period between wear periods. Lens rotation will be assessed over time with a slit lamp as well as with an automated lens tracking software. Subjective comfort, vision and handling will be assessed using the VAS questionnaire at fitting for each wear period. High Luminance High Contrast LogMAR VA will be assessed. Subjects will not have access to the study lenses following completion of the protocol.

[redacted]

4.3. Enrollment Target and Study Duration

This study will have an enrollment target of approximately 7 subjects, with a target of at least 5 to complete. The study will be conducted at 1 clinical site. A subject will be considered enrolled upon signing of the informed consent form.

There will be 2 visits in total per subject; total study duration including the enrollment period is expected to be approximately 6 weeks. Subjects who are discontinued prior to the final evaluation may be replaced at the discretion of the study sponsor. The investigation will end at the time when all visits have been completed for all enrolled subjects and the study data is locked.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

The study lenses will be worn bilaterally in a randomized fashion using a 2×2 crossover design.

A computer-generated randomization scheme will be used to randomly assign subjects to one of two unique sequences of lens wear (AO1DfA/DT1fA or DT1fA/AO1DfA) using an allocation ratio of 1:1 between lens sequences. [redacted]

The randomized assignment of subjects will be performed at the first visit prior to the first fitting. The Clinical site will follow the randomization scheme provided and will not pre-select or assign subjects. The following must have occurred prior to randomization:

- Informed consent must have been obtained
- The subject must have met all inclusion and exclusion criteria
- The subject history and baseline information must have been collected

[redacted]

5.2. Masking

This is a single-masked trial. Subjects will be masked to both study lenses. The study staff responsible for choosing the appropriate lens (site investigators or other site personnel) as per the randomization scheme will remove the foil from the packaging prior to providing lenses to subjects for lens insertion, so that the subjects may remain masked throughout the study.

Investigators and site personnel will not be masked to the study lenses due to the difference in packaging and lens markings.

5.3. Procedures for Maintaining and Breaking the Masking

Not applicable. As this is a non-dispensing trial, there is no foreseen situation in which the site would need to inform the subject of what contact lens they are wearing.

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Acuvue® Oasys 1-Day for Astigmatism (Test)	Dailies® Total 1 for Astigmatism (Control)
Test Article Form	Soft toric contact lenses	
Description	Standard marketed lenses	
Manufacturer	Johnson & Johnson Vision Care, Inc.	Alcon Inc.
Packaging Form	Blister packaging with sterile packing solution	Blister packaging with sterile packing solution
Packaging Solution	Optimized Borate Buffer (OBB) solution	Packaged in solution containing wetting agents
Lens Material	senofilcon A	delefilcon A
Sphere Powers (DS)	Marketed SKUs (+4.00 to -6.00)	
Cylinder Powers (DC)	Marketed SKUs (0.75 to 2.50)	
Cylinder Axes (°)	Marketed SKUs	
Nominal Water Content (%)	41	Variable
Nominal Base Curve (mm)	8.5	8.6
Lens Diameter (mm)	14.3	14.5
Fiducial marks	6 and 12 o'clock fiducial lines	6 o'clock fiducial line
Dk	103	140
Wear Modality in Current Study	Daily wear	
Replacement Frequency in Current Study	Daily disposable	
Commercially available	Yes	Yes

The site will be acquiring and using the commercially available lots to match the prescription per subject.

6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 2: Ancillary Supplies

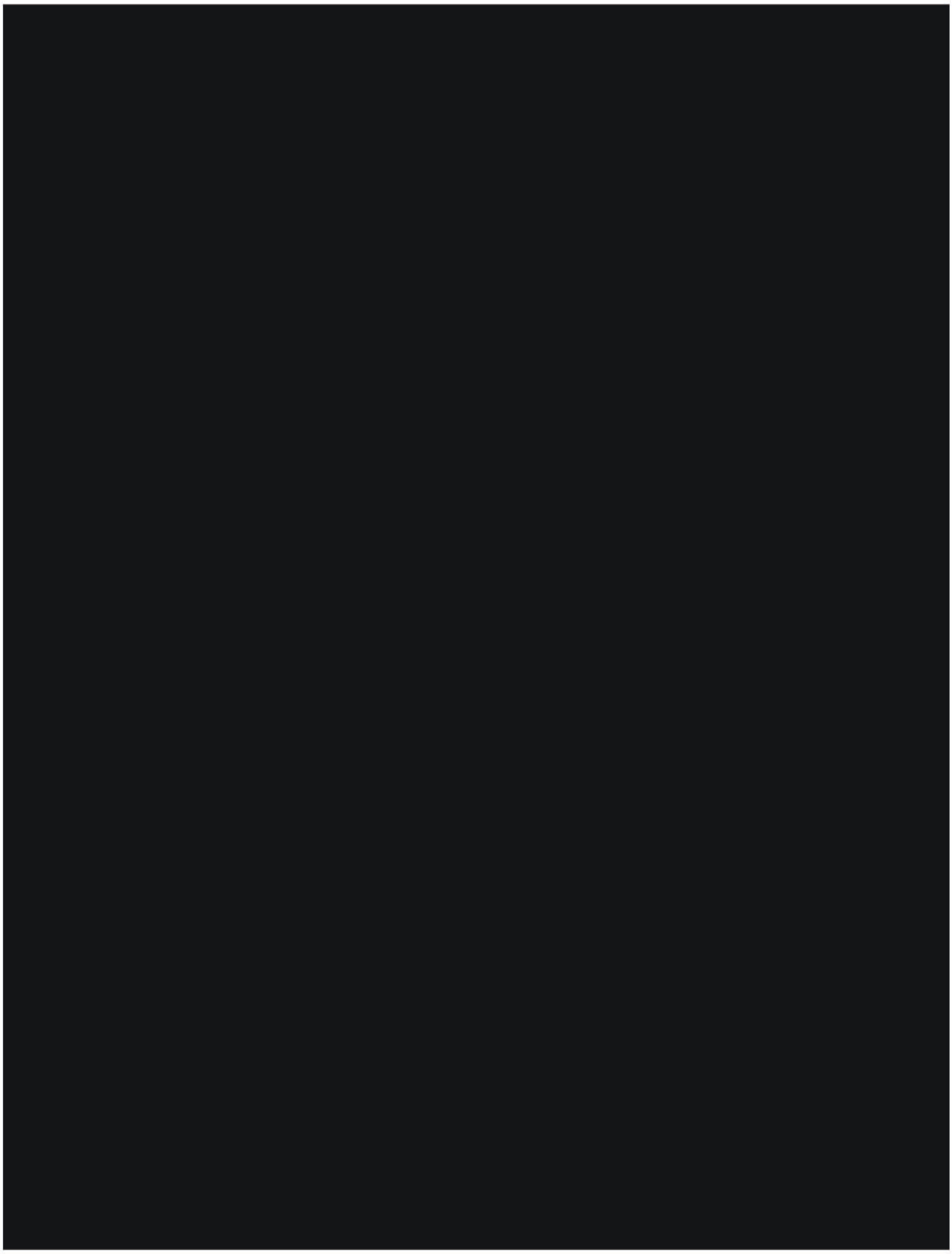
	Non-Preserved Saline
Solution Name/Description	Astroplast Ultra Saline 20ml Pods or similar
Manufacturer	Wallace Cameron International Ltd
Preservative	None

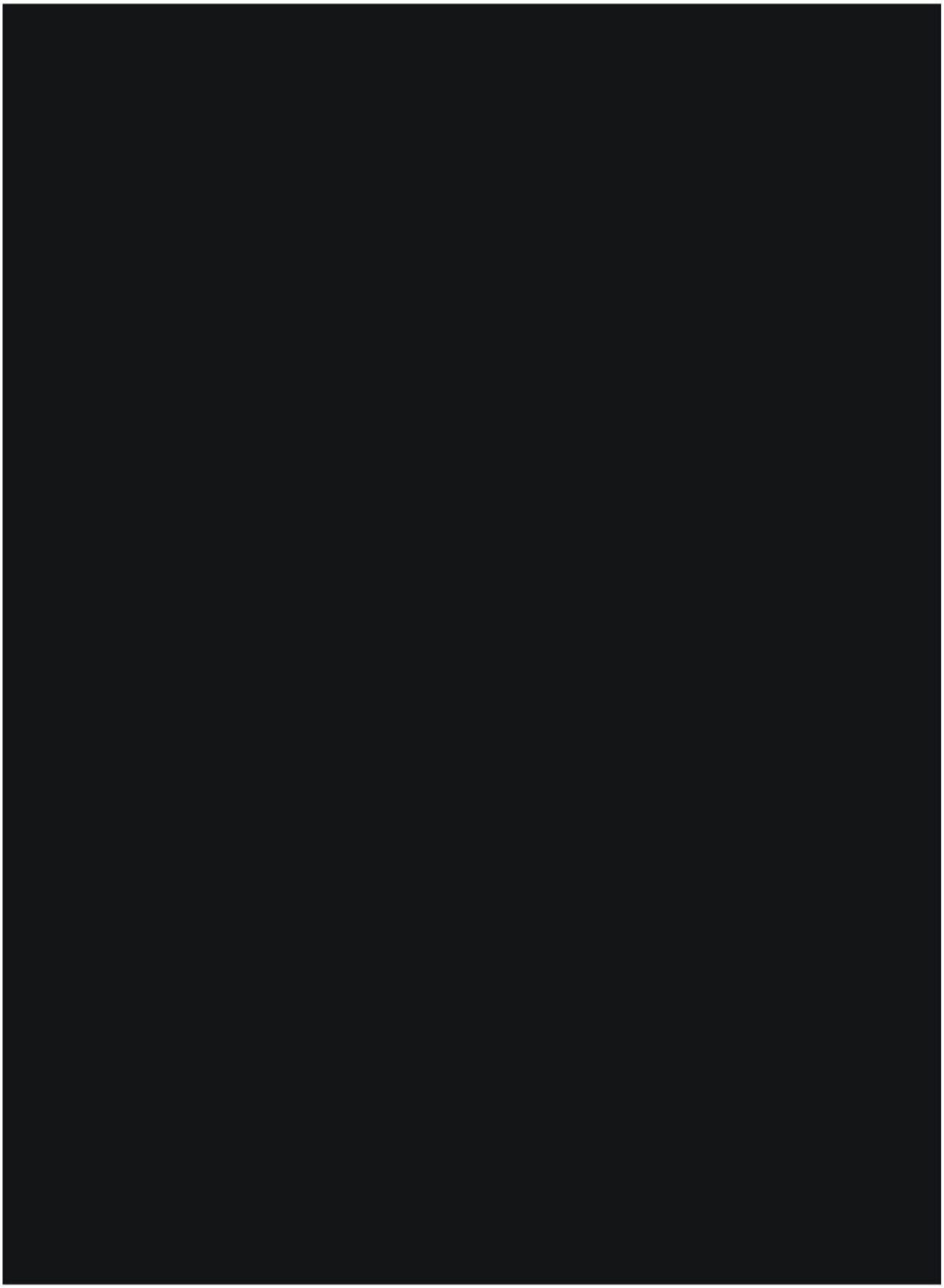
The sites will be acquiring the ancillary supplies as needed for the study including lens cases or fluorescein strips.

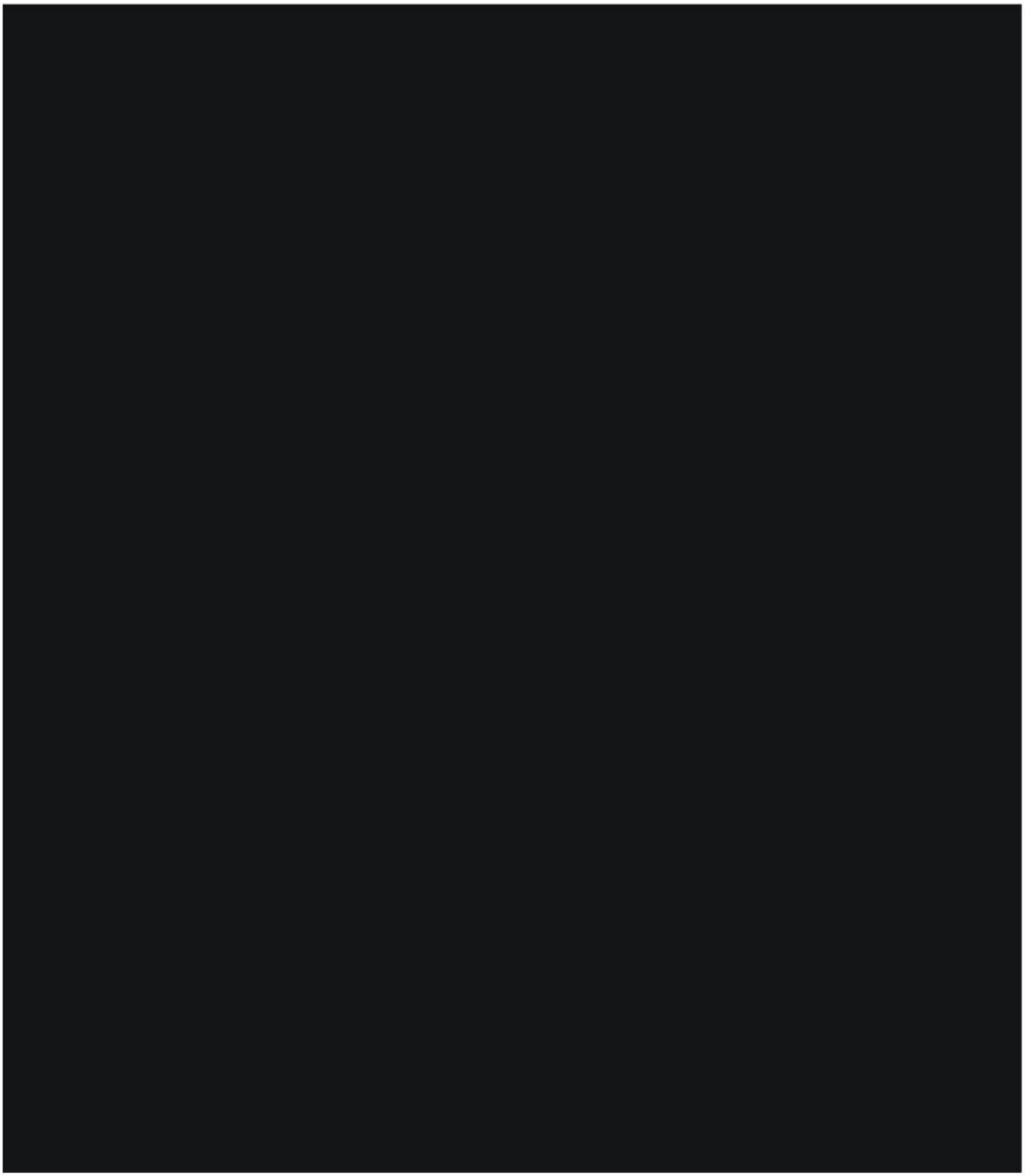
6.3. Administration of Test Articles

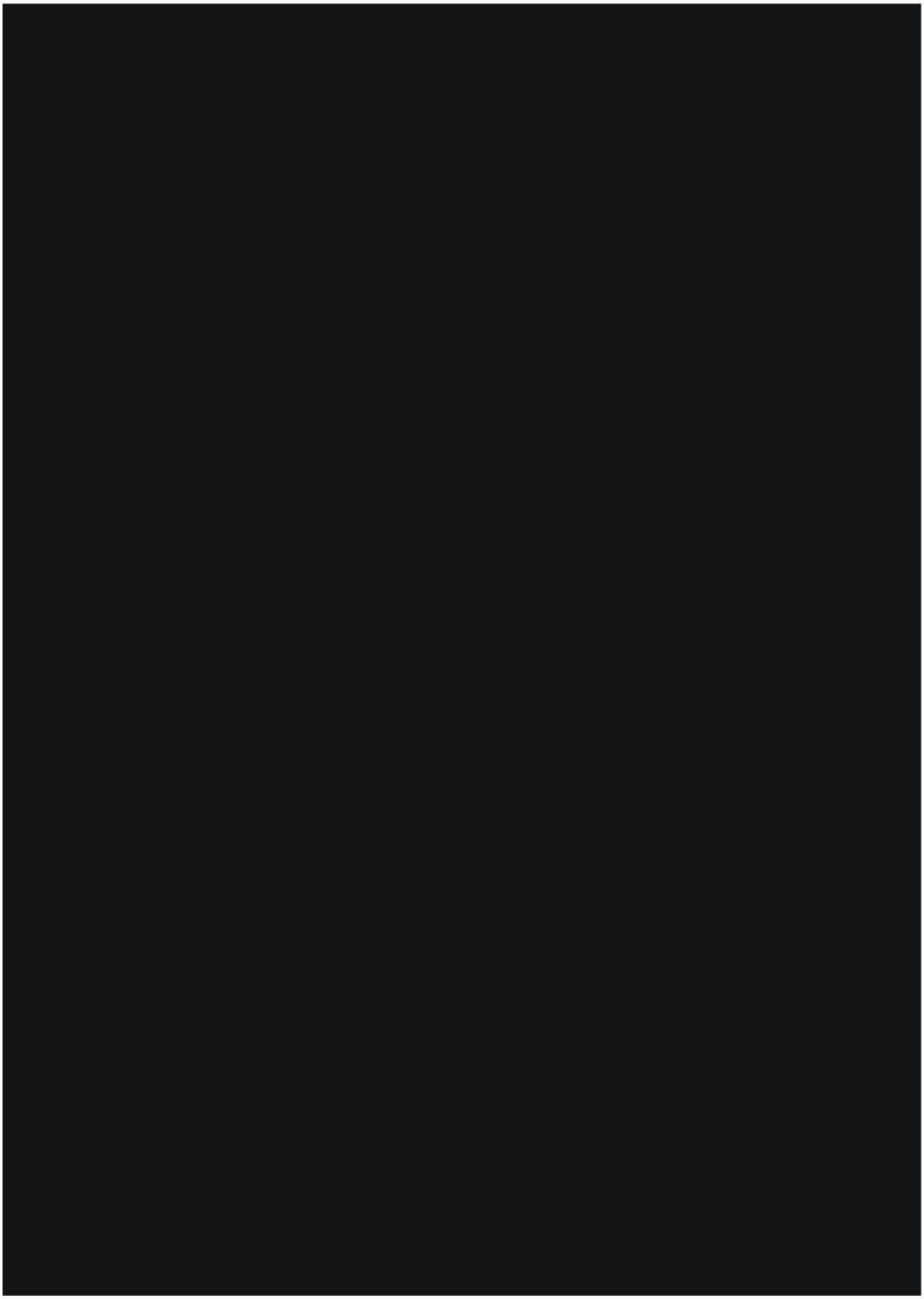
Test articles will be dispensed to subjects meeting all eligibility requirements, for in-office wear only as part of the requirements set forth in this clinical protocol.

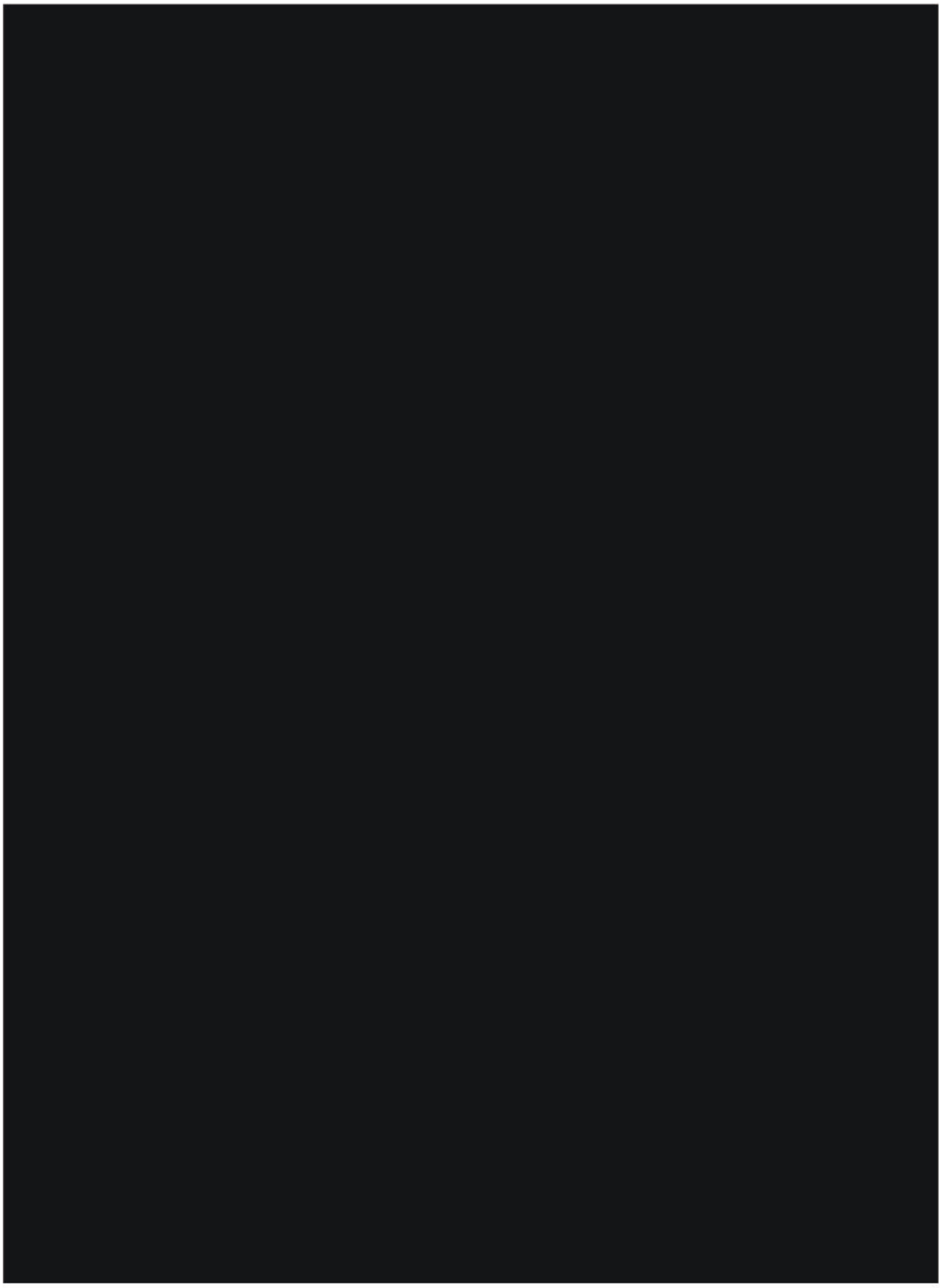
[redacted]

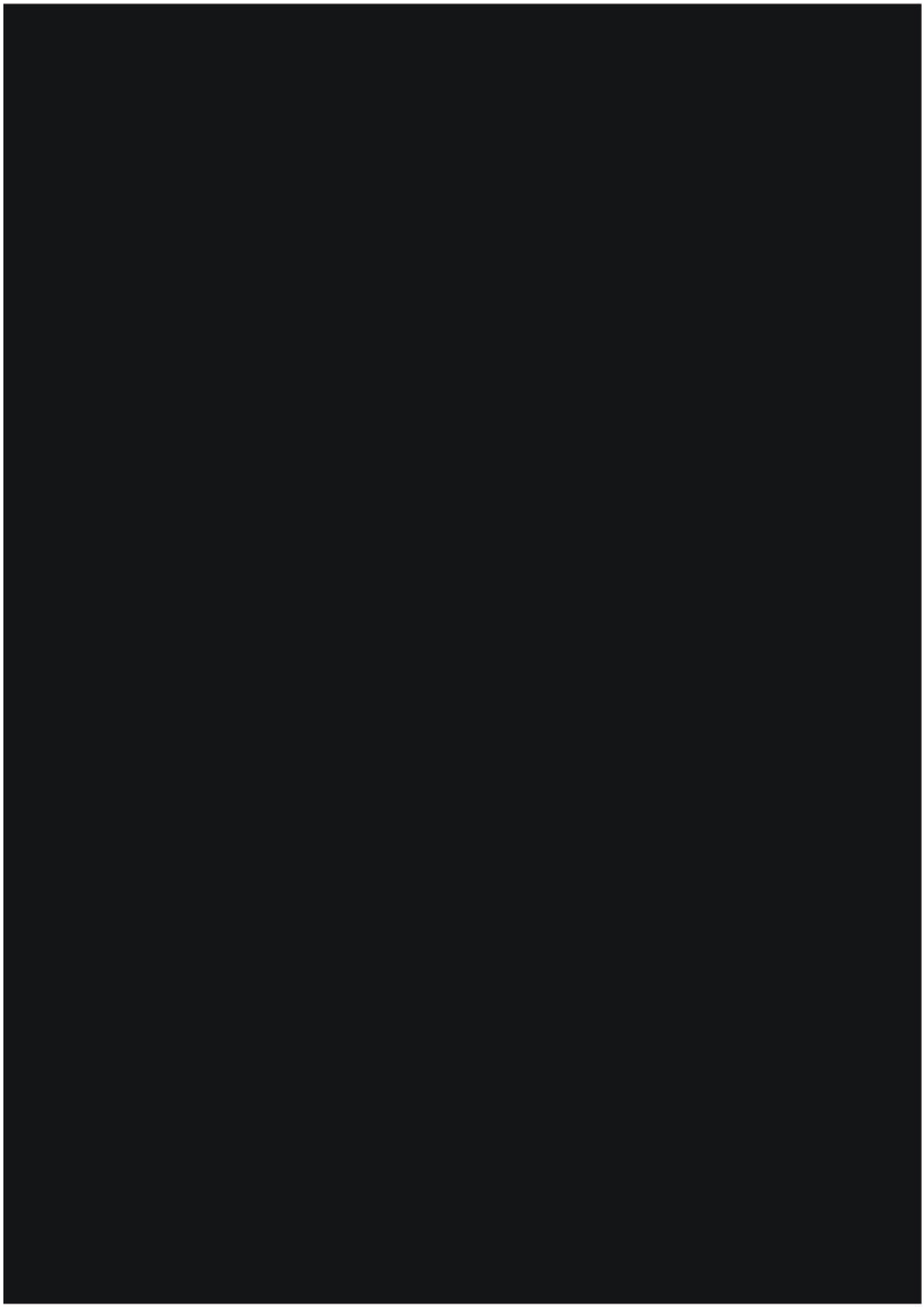












[redacted]

[redacted]

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 from the study for any reason described in section .
- completed all visits through the final visit (Visit 2).
- If all visits were completed but an additional visit is considered necessary for subject care, follow the requirements for unscheduled visits in section .

8.2. Withdrawal/Discontinuation from the Study

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

- 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 necessitating 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 missed any study visits
- 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.
- Make arrangements for subject care, if needed, due to their study participation

Additional subjects 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 concomitant interventions for this study include ocular medications of any kind, or any systemic medications that would normally contraindicate contact lens wear or may otherwise compromise study endpoints.

9.1. Systemic Medications

Certain systemic medications are known to have a higher likelihood to interfere with contact lens wear, chiefly by disrupting the tear film.

A summary of disallowed systemic medications is shown in . Subjects with a history of taking these medications will be allowed to enroll only if:

- The medications have been taken on a continual, routine basis for at least 6 months, and
- The subject has demonstrated successful contact lens wear during this time.

Or:

- The subject was taking the medication on a temporary basis and ceased taking that medication at least 2 weeks prior to signing the informed consent (this is considered sufficient time for the medication to have left the body prior to enrollment).

Subjects with a history of taking medications listed in on a long-term, routine basis for less than 6 months will not be allowed to participate in the study.

Table 4: Disallowed systemic medications

Class of Drug	Common Indication(s)	Common Examples
Estrogens (not including contraceptive medication)	Menopause, osteoporosis, vaginitis	Vagifem, Estrace, Climara, Vivelle-Dot, Premarin, Minivelle, etc.
Anticholinergics	Irritable bowel syndrome, Parkinson's disease, peptic ulcer, cystitis, nasal congestion, cold symptoms, overactive bladder, COPD	Bentyl, Spiriva, Atrovent, Hyosyne, Levsin, Symax Fastab, Symax SL, Homax SL, Cogentin, Transderm Scop, etc.
Beta-blockers	Hypertension, angina, heart attack, migraine, atrial fibrillation, adrenal cancer, essential tumor, glaucoma	Toprol XL, Lopressor, Tenormin, Propranolol, Timoptic, Trandate, Inderal LA, etc.
Psychotropics	Antipsychotic (schizophrenia, mania), antidepression, antiobsessive, antianxiety, mood stabilizer, stimulants (ADHD)	Zoloft, Celexa, Prozac, Lexapro, Effexor, Cymbalta, Ativan, Xanax, Desyrel, Wellbutrin, etc.
Vitamin A analogs	Cystic acne	Isotretinoin

Examples of disallowed systemic antihistamines are given in . Subjects with a history of taking systemic antihistamines will be allowed to enroll only if:

- They have taken antihistamines continuously for at least 2 weeks, and
- They have demonstrated successful wear while taking the medication

Or:

- They stopped taking the medication for at least 2 weeks prior to enrollment.

Table 5: Disallowed systemic antihistamines

Class of Drug	Common Indication(s)	Common Examples
Antihistamines	Allergic rhinitis, sedation, hives, allergic conjunctivitis, skin allergy, itching, motion sickness	Hydroxyzine, Promethagan, Phenadoz, Vistaril, Claritin, Zyrtec, Astepro, Astelin, Optivar, Allegra, Benadryl, etc.

10. DEVIATIONS FROM THE PROTOCOL

Investigator will notify study sponsor upon identification of a protocol deviation. 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, to the IEC/IRB.

If the deviation potentially impacts the safety of subject or changes the technical integrity of the study, then it must be reported to IEC/IRB. This is a "Major Deviation". Deviations that contradict the information contained in the Informed Consent/Assent forms will be considered Major Deviations.

Minor deviations have no substantive effect on subject safety or technical integrity of the study. They are often logistical in nature.

Protocol waivers are prohibited.

lists examples of deviations that will constitute major and minor protocol deviations for this study.

Table 6: Examples of major and minor protocol deviations

Deviation category	**Major deviation**	**Minor deviation**
Out-of-window visit (applies to wear periods only, i.e. not washout period)	Visit attended > 2 days out of visit window defined in study procedures	Visit attended ≤ 2 days out of visit window defined in study procedures

In the case of a major protocol deviation, the decision of whether or not the subject will be excluded from the Per-Protocol analysis population will be made at the time of cohort review. The list of major deviations with potential impact on the primary endpoint will be flagged separately and used to define the per protocol population.

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, DMC, and JJVC Safety Management Team, the study may be terminated. This potential stopping rule is established based on our trial involving approximately 200 subjects wearing the investigational soft contact lens for up to 3 years with an assumed MK rate that is below 0.2% per subject-year. The rate of 0.2% per subject-year is the established rate for extended wear lenses in adults, which was requested by the FDA as a criterion for evaluating a contact lens for pediatric use in an FDA response to a pre-IDE submission. To be conservative, 200 independent subject years were used in the calculation. The probability of observing 2 cases or

more incidents of MK is 0.061, and 3 cases or more incidents of MK is 0.007 (given an MK rate of 0.2% per subject year).

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 subject 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 and will follow the internal applicable quality review process and will notify the IEC/IRB. 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 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 the lens was inserted.
- Any related AE number if applicable.
- Detailed complaint description (scheduled/unscheduled visit, wear time, symptoms, resolution of symptoms, etc.).
- Eye Care Provider objective (slit lamp) findings if applicable.
- Confirmation of product availability for return (and tracking information, if available), or rationale if product is not available for return [redacted]

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 apply 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 medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated."
NOTE: This definition includes events related to the investigational medical device or the comparator, and to the procedures involved. For users or other persons, this definition is restricted to events related to investigational medical devices.[1]

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.

NOTE: 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 adverse event that led to any of the following:

- Death
- Serious deterioration in the health of the subject that resulted in any of the following:
  - Life-threatening illness or injury
  - Permanent or persistent impairment of a body structure or a body function
  - Hospitalization or prolongation of patient hospitalization
  - Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.
  - Chronic disease
- Foetal distress, foetal death or a congenital physical or mental impairment of birth defect.

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 – are defined as events that are symptomatic and warrant discontinuation (temporary or permanent) of the contact lens wear

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

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

Non-Significant Adverse Events – are defined as those events that are usually asymptomatic and usually do not warrant discontinuation of contact lens wear but may cause a reduction in wear time. However, the Investigator may choose to prescribe treatment 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
- Hordeolum
- Any corneal event not explicitly defined as serious or significant adverse event, which necessitates temporary lens discontinuation < 2 weeks

Adverse Device Effect (ADE) – An ADE is an "adverse event related to the use of an investigational medical device."
NOTE 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.
NOTE 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.
NOTE 3: This includes 'comparator' if the comparator is a medical device.

Serious Adverse Device Effect (SADE) - Any adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Unanticipated Serious Adverse Device Effect (USADE): serious adverse device effect (SADE) which by its nature, incidence, severity or outcome has not been identified in the current risk assessment. [USADE is synonymous with UADE below from the United States (US) Code of Federal Regulations (CFR)[3].]
NOTE 1: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment.

Unanticipated Adverse Device Effect (UADE) – A UADE is 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. [UADE is synonymous with USADE above from ISO 14155[1].]

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, or related)
- Adverse Event Severity – Adverse event severity is used to assess the degree of intensity of the adverse event (mild, moderate, or severe)
- Outcome – not recovered or not resolved, recovering or resolving, recovered or resolved with sequelae, recovered or resolved, death related to adverse event, or unknown.
- Actions Taken – none, temporarily discontinued, permanently discontinued, or other.

Causality Assessment

Causality Assessment – A determination of the relationship between an adverse event and the test article, study treatment, or the study procedures. The test article, study treatment, or study procedures relationship for each adverse event should 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 not likely.
- 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.

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) begin 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 and 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 (where appropriate), 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, if the AE is related to the visual system.

Upon discovery of an AE that is deemed 'possibly related' or 'related' to the test article or study procedures (whether related to the visual system or not), an AE review form [redacted] must be completed. Additional dated and initialed entries should be made at follow-up evaluations. Separate forms must be completed for each eye if the AE is bilateral.

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 subject will be referred to the appropriate health care provider. The Investigator will use his/her clinical judgment as to whether 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. Non-ocular adverse events

that are not related to the test article, study treatment, or study procedures may be recorded as "ongoing" without further follow-up.

13.4. Reporting Adverse Events

The Investigator will notify the Sponsor of an adverse event by EDC System, e-mail, 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. The report will comment whether the adverse event was considered to be related to the test article, study treatment or study procedures.

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 EDC System, e-mail 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.

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 to 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 study will be discontinued after the event is recorded as an Adverse Event. Once discontinued, pregnant subject and their fetuses will not be monitored for study related purposes. Pregnant subjects 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

Statistical Analysis will be undertaken by the sponsor or under the authority of the sponsor. A general description of the statistical methods to be implemented in this clinical trial is outlined below.

Descriptive summary tables (descriptive statistics and/or frequency tables) will be provided for all demographic and baseline characteristics, efficacy variables and safety variables. For continuous endpoints, the descriptive statistics will include the number of subjects and/or eyes (as appropriate), mean, standard deviation (SD), median, and minimum and maximum. For binary or categorical endpoints, the frequency distribution with the number and percentage of subjects and/or eyes (as appropriate) in each category will be calculated. Graphic displays may also be used to summarize the data. Unscheduled visits will be summarized separately.

All data summaries and statistical analyses will be performed using the SAS software Version 9.4 or higher (SAS Institute, Cary, NC)[5].

14.2. Sample Size Justification

This study was not designed or powered to test any statistical hypotheses with respect to distance (4m) visual acuity. As this will be the first study that will utilize the tracking software (Open Source Physics – OSP) a total of 5 subjects (10 eyes) to complete the study was based on clinical considerations and operational feasibility. A total of 5 subjects under a 2×2 crossover design provides sufficient data to evaluate the efficiency of this new software.

14.3. Analysis Populations

Intention-to-Treat (ITT) Population:
Intention-to-treat population will include all randomized subjects. Subjects will be analyzed as per planned randomized treatment.

Safety Population:
All subjects who are administered any study intervention. Subjects will be analyzed as per actual treatment received.

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

14.4. Level of Statistical Significance

Not applicable. No hypothesis testing will be performed for any endpoints in this study.

14.5. Statistical Analyses

Handling of Missing Data
All data summaries and statistical analysis will be conducted using the observed case data without multiple imputation. The count of missing data will be provided in each listing and table provided.

14.6. Efficacy Analyses

All efficacy endpoints will be summarized for both the ITT and per-protocol population using observed case data without multiple imputation.

Primary Efficacy Endpoint

1. Distance Visual Acuity

Distance (6m) monocular HLHC logMAR visual acuity at fitting will be summarized and presented only descriptively by lens type and timepoint (if applicable). Summary statistics are described in section 14.1

Secondary Efficacy Endpoint

Not applicable.

Other Efficacy Endpoints

1. Lens orientation measured over time with an automated lens tracking system following intentional misalignment Data resulting from the processing of the videos of each subject eye (for each lens), will be summarized by parameter (rotation error magnitude [range: 0° to 180°] and rotation error direction [base temporal or nasal]). The video processed will be approximately 5 minutes per eye per lens. The tracking software will measure the parameters at 5-second intervals, totaling for a plan of 60 observations per eye per lens. Rotation error magnitude is a continuous data point while the rotation error direction is nominal categorical data. Signed rotation will be derived based on rotation error magnitude and direction and will be included as part of the external data file detailed in section 15. Parameter data (rotation error magnitude, signed rotation, and rotation direction) reported (or derived) from the automated tracking system will be summarized as per section 14.1.

2. Lens orientation recorded with an automated lens tracking system following eye movements
   In addition to collecting rotation error magnitude and direction following intentional misalignment, rotation error magnitude and direction will be recorded in each of the 8 cardinal gaze directions before and after eye movement. The singed rotation will be derived in the same manner as described above. Summaries will be provided for each parameter (rotation error magnitude, singed rotation, and rotation direction), timepoint (before and after eye movement) and gaze separately. Additional summaries will be provided for the 8 gazes combined.

   The 8 cardinal gazes are:
   - Up and to the right
   - Upward
   - Up and to the left
   - Right
   - Left
   - Down and to the right
   - Downward
   - Down and to the left

3. Settling Time following intentional misalignment
   The time (in seconds) required for the lens to settle (defined as returning to within 5 degrees of initial settled position) after intentional misalignment will be presented descriptively and summarized separately for each study lens. Summary statistics are described in section 14.1.

4. Toric Lens Orientation
   The distribution (counts, percentages) of eyes for the toric Orientation (in degrees) at 1- and 3-minutes after lens insertion will be summarized at fitting and by lens type. Summary statistics are described in section 14.1.

5. Subjective Vision, Comfort and Handling Scores
   Vision, comfort, and handling items will be summarized separately and presented only descriptively by lens type and timepoint (if applicable). Summary statistics are described in section 14.1.

14.7. Safety Analyses

All safety endpoints will be summarized for the safety population using observed case data.

Primary Safety Endpoint

Not applicable.

Secondary Safety Endpoint

Not applicable.

Other Safety Endpoints

1. Slit Lamp Findings
   Slit Lamp Findings (SLF) related to study lens wear will be assessed for each eye at all study visits (scheduled and unscheduled). SLFs will be evaluated and graded using the Efron Grading scale. The Efron grading scale is interval continuous from 0 to 4, where 0 represents the absence of findings and findings > 0 representing successively worse findings. Slit lamp will be used to assess the following:
   - Corneal infiltrates
   - Conjunctival redness
   - Limbal redness
   - Corneal neovascularization
   - Epithelial microcysts
   - Corneal oedema
   - Corneal staining
   - Location of staining
   - Conjunctival staining
   - Blepharitis
   - Meibomian Gland dysfunction
   - Mucin ball

   Each study lens and parameter will be summarized separately and presented descriptively.

2. Adverse events (AEs)
   Details for AEs will be provided through listings. This listing will include both ocular and non-ocular.

14.8. Interim Analyses

Not applicable.

14.9. 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 a Sitero 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.

External data sources for this study include: Video files and Excel data files for lens orientation analysis per subject. Each video recording will show a single eye and its surrounding eyelid area (see Appendix G for example) without having personally identifiable information in the image or the filename. The video files will be provided in a standard video format (eg. mpeg). Video files are processed using tracking software (Open Source Physics – OSP) to estimate the lens orientation over a 5-minute period of recovery from intentional misalignment from the settled position. The rotation error direction and magnitude relative to two reference positions (relative to 6 o'clock position, and relative to initial settled position) will be provided. The signed rotation will be derived using rotation error magnitude and direction. Data is planned to be provided at 5 second increments, but alternative increments may be found to be necessary once data collection commences.

Additionally, lens orientation (direction and magnitude of rotation error relative to 6 o'clock position, and relative to initial settled position) following eye movements in 8 directions of gaze will be provided in a separate Excel spreadsheet.

[redacted]

The clinical data will be recorded on dedicated eCRFs specifically designed to match the study procedures for each visit. Only specifically delegated staff can enter data on a CRF. 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 ISO14155:2020.[1]

15.2. Subject Record

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

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

- reason for early discontinuation of test article or withdrawal from the study, if applicable

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

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

15.3. Trial Registration on ClinicalTrials.gov

This study will be registered on ClinicalTrials.gov by the sponsor.

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, including 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.

16.4. Data Monitoring Committee (DMC)

Not applicable

17. CLINICAL 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 versions, 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. Subjects will only be enrolled if the subject is fully able to understand the risks, benefits, and potential adverse events of the study and provide their consent voluntarily.

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, according to ISO 14155:2020,[1] and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles of the Declaration of Helsinki 64th WMA General Assembly 2013[2] and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with applicable regulatory requirements.

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

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

- Final protocol.
- Sponsor-approved informed consent form (and any other written materials to be provided to the subjects)
- Investigator's Brochure (or equivalent information).
- 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, 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 revisions
- 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 revisions
- 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 revisions that increase subject risk, the revisions 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, or their representative, 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, [2] and ISO 14155:2020[1] 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 subjects 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 their 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 Health Information Portability and Accountability Act (HIPAA) in the United States 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 ISO 14155:2020,[1] 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 ISO 14155:2020,[1] 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 two (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 two (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 Clinical Research Agreement. The Research Agreement will be signed by the Principal Investigator and a JJVC management representative prior to study initiation.

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.

JJVC reserves the right to withhold final remuneration until all study related activities have been completed, such as:

- Query resolution.
- Case Report Form signature.
- Completion of any follow-up action items.

21. PUBLICATION

The study will be listed on clinicaltrials.gov.

[redacted]

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

1. ACUVUE® OASYS 1-Day for Astigmatism contact lenses from JJVCI
2. Dailies® Total1 for Astigmatism contact lenses from Alcon Inc.

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 ACUVUE OASYS® for ASTIGMATISM contact lenses 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 the patient.

A. How to Determine Lens Cylinder and Axis Orientation

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' symmetrical stabilization design, 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 patient's refractive axis, it is not advisable to over-refract because of the difficulty in computing the resultant power. In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible.

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 power that is ≤ 0.25D from the vertex-corrected refractive cylinder.

Case Examples:

Example 1

Manifest (spectacle) refraction:

O.D. -2.50D / -1.25D x 180° 20/20

O.S. -2.00D / -1.00D 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. If the lens has not yet stabilized, recheck until stable.

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. If the lens has not yet stabilized, recheck until stable.

Here is the Rx prescribed:

O.D. -2.50D / -1.25D x 180°

O.S. -2.00D / -0.75D x 180°

Example 2

Manifest (spectacle) refraction:

O.D. -3.00D / -1.00D x 90° 20/20

O.S. -4.75D / -2.00D x 90° 20/20

Choose diagnostic lenses of -3.00D / -0.75D x 90° for the right eye and -4.50D / -1.75D x 90° for the left eye, the nearest lenses available to the spherical power, cylinder power, and axis needed. For the left eye, since the manifest refraction called for -4.75D, compensating for vertex distance the sphere is reduced by 0.25D to -4.50D. The cylinder power will be -1.75D. 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. If the lens has not yet stabilized, recheck until stable.

Right Eye:

The orientation mark on the right lens rotates left from the 6 o'clock position by 10° 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. -3.00D / -0.75D x 100°

Left Eye:

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

Compensate for the 10° axis drift by subtracting it from the manifest refraction axis.

Here is the Rx prescribed:

O.S. -4.50D / -1.75D x 80°

If vision is 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).

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download from 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 ACUVUE OASYS® for PRESBYOPIA Contact Lenses. Wear may not be optimal for such activities 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 pass their state driver's license requirements with these lenses should be advised to not drive with this correction OR may require that additional over-correction be prescribed.

These 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.

These lenses are available in the following ADD powers:

- Lens "LOW" = "low" near ADD lens (Max +1.25 ADD)
- Lens "MID" = "medium" near ADD lens (Max +1.75 ADD)
- Lens "HIGH" = "high" near ADD lens (Max +2.50 ADD)

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. Vertex distance compensation is generally only necessary for refractions ≥ ± 4.00D, but may sometimes also be required for lower refractions in the case of large vertex distances. Determine the spherical equivalent distance prescription for a multifocal patient. Determine the eye dominance using one of the methods below:

Method 1 (preferred): Determine which eye will accept the added power with the least reduction in vision while both eyes are open. Place a hand-held trial lens equal to +1.50D 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 +1.50D lens over the right or left eye, which is the non-dominant eye.

Method 2: 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.

C. Select the Initial Trial Lens

1. Determine the following:
   - Eye dominance (the methods described in MONOVISION FITTING GUIDELINES may be used)
   - Spherical equivalent distance prescription (vertex corrected if necessary and rounded to less minus if between powers)
   - Near ADD
2. For each eye, select the trial lens distance power that is closest to the patient's distance spherical equivalent. Vertex distance compensation is generally only necessary for refractions ≥ ± 4.00D, but may sometimes also be required for lower refractions in the case of large vertex distances.
3. Select the initial trial lens as follows:
   - For each eye select the trial lens distance power that is closest to the patient's distance spherical equivalent.
   - 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 "HIGH" near ADD on the dominant eye and a "HIGH" near
4. Allow the lenses to settle for a minimum 10 minutes.
5. Assess distance and near vision binocularly and monocularly.
6. Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near.
7. 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.
8. 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 PATIENT MANAGEMENT section).

D. Multifocal Troubleshooting

Unacceptable Near Vision:

Determine the amount of additional plus, or less minus, over one or both eyes that is acceptable, while checking the effect on distance and near vision. If vision is still not acceptable, change the non-dominant eye to the next highest ADD power.

Unacceptable Distance Vision:

Determine the amount of additional minus, or less plus, over one or both eyes that is acceptable while checking the effect on distance and near vision. If vision is still not acceptable, change the dominant eye to the next lowest ADD power. If the patient is wearing two low ADD lenses, change the dominant eye to a sphere lens with a power equal to the spherical equivalent distance prescription.

Unacceptable Distance and Near Vision:

Determine the amount of additional plus and/or minus over one or both eyes that is acceptable while checking the effect on distance and near vision. If additional plus and/or minus is not required, change the lens power in the dominant eye to the next lowest ADD power and the lens power in the non-dominant eye to the next highest ADD power, if applicable.

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 from 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 amounts of uncorrected 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 pass 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, 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.

   Example:

   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 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.

PATIENT MANAGEMENT

Dispensing Visit

- **PROVIDE THE PATIENT WITH A COPY OF THE PATIENT INSTRUCTION GUIDE FOR THESE LENSES. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE (DISPOSABLE OR FREQUENT REPLACEMENT).**
- Recommend an appropriate cleaning and disinfecting system and provide the patient with instructions regarding proper lens care. Chemical or hydrogen peroxide disinfection is recommended.
- Follow the accepted standard of care in fitting and following up with your patient.
- Schedule the appropriate follow-up examination.
- Preferably, at the follow-up visits, lenses should have been worn for at least six hours.

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, lens replacement schedule, and proper lens care and handling procedures.
- 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: More frequent or additional follow-up visits may be recommended for patients on an extended wear schedule.

- Preferably, at the follow-up visits, lenses should be worn for at least six hours. If the lenses are being worn for continuous wear, the examination should be performed as early as possible on the morning following overnight wear.

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.

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.
- Having 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 with 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 from www.acuvue.com.

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.

For Daily Wear:

Patients tend to overwear 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

For Extended Wear:

It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

These lenses have been approved for extended wear up to 6 nights/7 days of continuous wear. Not all patients can achieve the maximum wear time.

For Therapeutic lens wear, close supervision by the Eye Care Professional is necessary. These lenses can be worn for extended wear for up to 6 nights/7 days of continuous wear. The Eye Care Professional should determine the appropriate wearing time and provide specific instructions to the patient regarding lens care, insertion, and removal.

REPLACEMENT SCHEDULE

For Lenses Prescribed for Frequent Replacement:

When prescribed for daily wear (frequent replacement), it is recommended that the lenses be discarded and replaced with a new lens every 2 weeks. However, the Eye Care Professional is encouraged to determine an appropriate replacement schedule based upon the response of the patient.

For Lenses Prescribed for Disposable Wear:

When prescribed for disposable wear, the replacement schedule should be determined by the Eye Care Professional based upon the patient's history and their ocular examination, as well as the practitioner's experience and clinical judgment.

Once removed, it is recommended that the lens remain out of the eye for a period of rest of overnight or longer and be discarded in accordance with the prescribed wearing schedule. The Eye Care Professional should examine the patient during the early stages of extended wear.

LENS CARE DIRECTIONS

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

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.

For Lenses Prescribed for Frequent Replacement Wear:

The Eye Care Professional should review with the patient, lens care directions for cleaning, disinfecting and storing, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

For Lenses Prescribed for Disposable Wear:

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 replacement lenses or spectacles available.

Lenses should only be cleaned, rinsed, and disinfected on an emergency basis when replacement lenses or spectacles are not 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

During removal, if the lens sticks to the eye, 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 methyl ether cellulose. The plastic package is marked with the following:

- **ACUVUE OASYS®:** base curve, power, diameter, lot number, and expiration date
- **ACUVUE OASYS® for ASTIGMATISM:** base curve, power, diameter, cylinder, axis, lot number, and expiration date
- **ACUVUE OASYS® for PRESBYOPIA:** 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 the 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

In Canada: Johnson & Johnson Vision Care, a Division of Johnson & Johnson (Canada) Inc.
In USA: Johnson & Johnson Vision Care Inc.

Printed in USA
SAP Part Number: 20602135
Revision Date: 03/2023
Revision Number: A0-03-23-05

PACKAGE INSERT & FITTING INSTRUCTION GUIDE

ACUVUE® OASYS BRAND CONTACT LENSES WITH HYDRACLEAR® PLUS

ACUVUE OASYS® Brand Contact Lenses
ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM
ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA

senofilcon A Soft (hydrophilic) Contact Lenses
Visibility Tinted with UV Blocker
for Daily and Extended Wear

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.

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

JJVC CONFIDENTIAL

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SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DESCRIPTION
	Caution, Consult Instructions for Use
	Date of Manufacture
	Manufacturer
	Use-By Date (expiration date)
LOT	Batch Code
STERILE	Sterilized Using Steam Heat
	Indicates a Single Sterile Barrier System
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CYL	Cylinder
AXIS	Axis
CE 2797	CE Mark and Identification number of Notified Body
UK CA 0086	UK Conformity Assessment Marking and Identification Number of Notified Body
UV BLOCKING	UV Blocking
	Fee Paid for Waste Management
Rx Only	CAUTION: US Federal law restricts this device to sale by or on the order of a licensed practitioner
	Lens Orientation Correct

SYMBOL	DESCRIPTION
	Lens Orientation Incorrect (Lens Inside Out)
EC REP	Authorized Representative in the European Community
UK REP	Authorized Representative in the United Kingdom
	Contains Hazardous Substances
	Do Not Use if Package is Damaged
MD	Medical Device Symbol
	Package Opening Icon (Blister)
	Package Opening Icon (Carton)
L	"Low" near ADD
M	"Medium" near ADD
H	"High" near ADD
MAX ADD	"Near" ADD
LOW	"Low" near ADD
MID	"Medium" near ADD
HGH	"High" near ADD

Visit www.acuvue.com/guides for additional information about symbols.

DESCRIPTION

The ACUVUE OASYS® Brand Contact Lenses, the ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM, and the ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA are soft (hydrophilic) contact lenses available as spherical, toric, or multifocal lenses and include HYDRACLEAR® PLUS Technology. The lenses are made of a silicone hydrogel material containing an internal wetting agent with visibility tinted UV absorbing monomer.

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 transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.42
- Visible Light Transmittance: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability (Dk):

VALUE	METHOD
103 x 10^{-11} (cm^2/sec) (ml O_2/mL x mm Hg) @ 35°C	Fatt (boundary corrected, edge corrected)
122 x 10-11 (cm2/sec) (ml O2/ml x mm Hg) @ 35°C	Fatt (boundary corrected, non-edge corrected)

Lens Parameter Ranges:

- Diameter (DIA): 12.0 mm to 15.0 mm
- Center Thickness: varies with power
- Base Curve (BC): 7.85 mm to 10.00 mm
- Spherical Power (D): Daily Wear: -20.00D to +20.00D
  Extended Wear: -20.00D to +14.00D
- Multifocal ADD Power: +0.25D to +4.00D
- Cylinder: -0.25D to -10.00D
- Axis: 2.5° to 180°

Each lens is supplied in a foil-sealed plastic package containing borate buffered saline solution with methyl ether cellulose.

AVAILABLE LENS PARAMETERS

The ACUVUE OASYS® Brand Contact Lenses are hemispherical shells of the following dimensions:

Diameter (DIA): 14.0 mm

Center Thickness: Minus Lens - varies with power (e.g. -4.00D: 0.070 mm)
Plus Lens - varies with power (e.g. +4.00D: 0.168 mm)

Base Curve (BC): 8.4 mm, 8.8 mm

Powers (D): -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)
+6.50D to +8.00D (in 0.50D increments)

The ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM are hemispherical shells of the following dimensions:

Diameter (DIA): 14.5 mm

Center Thickness: Minus Lens - varies with power (e.g. -4.00D: 0.080 mm)
Plus Lens - varies with power (e.g. +4.00D: 0.172 mm)

Base Curve (BC): 8.6 mm

Powers (D): plano to -6.00D (in 0.25D increments)
-6.50D to -9.00D (in 0.50D increments)
+0.25D to +6.00D (in 0.25D increments)
Cylinder: -0.75D, -1.25D, -1.75D, -2.25D, -2.75D
Axis: 10° to 180° in 10° increments

The ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA are hemispherical shells of the following dimensions:

Diameter (DIA): 14.3 mm

Center Thickness: Minus Lens - varies with power (e.g. -4.00D: 0.070 mm)
Plus Lens - varies with power (e.g. +4.00D: 0.168 mm)

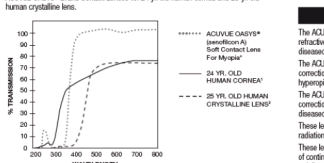
Base Curve (BC): 8.4 mm

Powers (D): -9.00D to +6.00D (in 0.25D increments)

ADD Powers (D): +1.25D (LOW), +1.75D (MID), +2.50D (HGH)

TRANSMITTANCE CURVE

ACUVUE OASYS® Brand Contact Lenses vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



*The data was obtained from measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-1.000 lens, 0.070 mm center thickness).

† Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, figure 2-21

‡ Wooler, 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. When hydrated and placed on the cornea for therapeutic use, the contact lens acts as a bandage to protect the cornea.

The transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

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.

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 ACUVUE OASYS® Brand Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.

The ACUVUE OASYS® Brand Contact Lens for ASTIGMATISM is indicated for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism.

The ACUVUE OASYS® Brand Contact Lens for PRESBYOPIA is indicated for the optical correction of distance and near vision in presbyopic, phakic, or aphakic persons with non-diseased eyes who may have 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.

These lenses have been approved for daily and extended wear for up to 6 nights/7 days of continuous wear. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

These lenses are also indicated for therapeutic use as a bandage lens for the following acute and chronic ocular conditions:

- For corneal protection in kid and corneal abnormalities such as entropion, trichiasis, tarsal scars, and recurrent corneal erosion. In addition, they are indicated for protection where sutures or ocular structure malformation, degeneration, or paralysis may result in the need to protect the cornea from exposure or repeated irritation.
- For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, and post-keratoplasty.
- For use as a barrier during the healing process of epithelial defects such as chronic epithelial defects, corneal ulcer, neurotrophic and neuroparalytic keratitis, and chemical burns.
- For post surgical conditions where bandage lens use is indicated such as post refractive surgery, lamellar grafts, corneal flaps, and additional ocular surgical conditions.
- For structural stability and protection in piggy back lens fitting where the cornea and associated surfaces are too irregular to allow for corneal rigid gas permeable (RGP) lenses to be fit. In addition, the use of the lens can prevent irritation and abrasions in conditions where there are elevation differences in the host/graph junction or scar tissue.

Lenses prescribed for therapeutic use may be worn for daily or extended wearing periods.

CONTRAINDICATIONS (REASONS NOT TO USE)

When prescribing contact lens wear for REFRACTIVE AMETROPIA USE, DO NOT USE these lenses when 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

For THERAPEUTIC USE, the Eye Care Professional may prescribe these lenses to aid in the healing process of certain ocular conditions, which may include these cited above.

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.

- Patients should be instructed not to wear their 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.[1]

- 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.

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

Specific Instructions for Use and Warnings:

- **Water Activity**

Instructions 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.

- **Soaking and Storing Your Lenses**

Instructions for Use

Use only fresh multi-purpose (contact lens disinfecting) solution each time the lenses are soaked (stored).

WARNING:

Do not reuse or "top off" old solution left in the lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss, or blindness. "Topping-Off" is the addition of fresh solution to solution that has been sitting in the case.

- **Discard Date on Multi-Purpose Solution Bottle**

Instructions for Use

– Discard any remaining solution after the recommended time period indicated on the bottle of multi-purpose solution used for disinfecting and soaking the contact lenses.

– The Discard Date refers to the time that the patient can safely use the contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

WARNING:

Using multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss, or blindness.

– To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.

– To avoid contaminating the solution, DO NOT transfer to other bottles or containers.

- **Rub and Rinse Time**

Instructions for Use

To adequately disinfect the lenses, the patient should rub and rinse the lenses according to the recommended lens rubbing and rinsing times in the labeling of the multi-purpose solution.

WARNING:

– Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.

– Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss, or blindness.

- **Lens Case Care**

Instructions for Use

– Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.

– Replace the lens case according to the directions provided by the Eye Care Professional or the manufacturer's labeling that accompanies the case.

– Contact lens cases can be a source of bacterial growth.

WARNING:

Do not store lenses or rinse lens cases with water or any non-sterile solution. Only fresh multi-purpose solution should be used to prevent contamination of the lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss, or blindness.

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 multifocal correction 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 unless otherwise indicated. 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, rinse, and dry hands before handling lenses. It is best to put on lenses before putting on makeup.
- DO NOT touch contact lenses with 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 contact 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. Slide the lens up the side of the bowl until it is free of the container.
- Do not touch the lens with fingernails.
- Close supervision is necessary for the Therapeutic use of these lenses. Ocular medications used during treatment with a bandage lens should be closely monitored by the Eye Care Professional. In certain ocular conditions, only the Eye Care Professional will insert and remove the lenses. In these cases, patients should be instructed not to handle the lenses themselves.

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. 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.
- Ask the Eye Care Professional about wearing lenses during sporting activities.
- The patient should be advised to never rinse the lenses in water from the tap. Tap water contains many impurities that can contaminate or damage the lenses and may lead to eye infection or injury.

Lens Care Precautions:

- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Always use fresh, unexpired lens care solutions and lenses.
- Do not change solution without consulting with your Eye Care Professional.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage these lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying (e.g. exposing the lens to air for 30 minutes or more) will reduce the ability of the lens surface to return to a wettable state. If the lens surface does become dried out, discard the lens and use a new one.

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 care
- 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 appropriate lens fitting instruction 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. Vertex distance compensation is generally only necessary for refractions ≥ ± 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.

- ACUVUE OASYS®: 8.4 mm/14.0 mm
- ACUVUE OASYS® for ASTIGMATISM: 8.6 mm/14.5 mm
- ACUVUE OASYS® for PRESBYOPIA: 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 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

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 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**).

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

Alcon	Package Insert for Alcon DAILIES TOTAL1™ for Astigmatism (delefilcon A) soft contact lenses for daily disposable wear	W900409251

IMPORTANT: This package insert is effective as of May 2020 and applicable to the delefilcon A contact lenses described below. Please read carefully and keep this information for future use.
This package insert 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 appropriate instructions that pertain to the patient's prescribed lenses. Alcon also recommends that patients receive a copy of the **Patient Instruction Booklet** for their prescribed lenses. Copies of this package insert and the **Patient Instruction Booklet** are available without charge from Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com.

Rx only

CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed Eye Care Professional.

PRODUCT DESCRIPTION

DAILIES TOTAL1™ for Astigmatism (delefilcon A) soft contact lenses are made of a lens material that is approximately 33% water and 67% (delefilcon A) polymer, a silicone containing hydrogel with added phosphatidylcholine. The core lens material containing 33% water transitions through a water gradient to a hydrogel surface layer that exceeds 80% water. Lenses contain the color additive copper phthalocyanine, and have a light blue-green tint that makes them easier to see when handling. This package insert applies to DAILIES TOTAL1™ for Astigmatism lenses with light absorbing chromophores (as identified in 'Contents' statement on carton labeling). Benzotriazole UV and UV-Vis absorbing monomers are used to block UV radiation and reduce transmittance of high energy visible light (HEVL) wavelengths in the range from 380 nm to 450 nm*.

Lens Properties

- Refractive Index (hydrated): 1.42
- Light Transmittance: 90% ± 5% for average over 380 to 780 nm
- HEVL Transmittance: ≤ 80%T at 420 nm (refer to Figure 1 for transmittance profile)*
- UV Transmittance: τUVB < 1.0 % (average percent transmittance over 280 nm to 315 nm)
  τUVA < 10.0 % (average percent transmittance over 315 nm to 380 nm)
- Oxygen Permeability (Dk): 140 barrer units, measured at 35 °C (intrinsic Dk - Coulometric method)
- Water Content: 33% by weight in normal saline

Lens Parameters

- Diameter Range: 13.0 to 15.0 mm
- Power Range: -20.00 to +20.00 D
- Base Curve Range: 8.0 to 9.2 mm

Lens Parameters Available[1]

DAILIES TOTAL1™ for Astigmatism (delefilcon A)

- Chord Diameter: 14.5 mm
- Center Thickness: 0.11 mm @ -3.00 D (varies with power)
- Base Curve: 8.6 mm
- Sphere Power: +4.00 to -6.00 D (0.25 D steps); -6.50 to -8.00 D (0.50 D steps)
- Cylinder Power: -0.75 D, -1.25 D, -1.75 D, -2.25 D
- Axis: 10° to 180°, in 10° steps

ACTIONS

When hydrated and placed on the cornea, DAILIES TOTAL1™ for Astigmatism (delefilcon A) soft contact lenses act as a refracting medium to focus light rays on the retina.

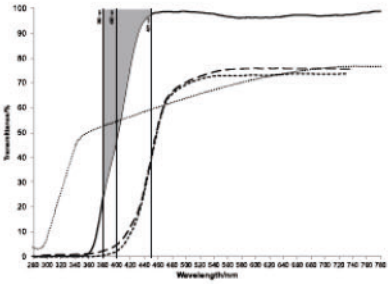
The lenses contain a combination of UV and UV-Vis blocking monomers to help protect against transmission of harmful UV radiation to the cornea and into the eye. For example, a lens with 0.09 mm center thickness (-3.00 D, thinnest projected parameter) blocks 97% of UVA radiation, and 99% UVB radiation average across the spectrum. The lenses reduce high energy visible light (HEVL) radiation reaching the back of the eye by about 33% in the range from 380 nm to 450 nm*. See Figure 1 for the transmittance profile of delefilcon A lenses with light absorbing chromophores (-3.00 D, thinnest projected parameter). The radiation transmittance will be further reduced with increasing lens 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.

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. High energy visible light filtering provided by delefilcon A soft contact lenses with light absorbing chromophores is additive to the natural crystalline lens. There is no demonstrated clinical benefit to a 33% reduction in visible light at wavelengths below 450 nm. The Eye Care Professional should be consulted for more information.

Figure 1 illustrates the transmittance of a lens with 0.09 mm center thickness (-3.00 D, thinnest projected parameter), a human cornea, a human lens, and the combined filtration effect of the contact lens and the human lens on retinal exposure. The shaded regions of the graph represent the integrated attenuation transmittance percentages of the delefilcon A lenses with light absorbing chromophores (-3.00 D, thinnest projected parameter) in the high energy visible light region (380 nm to 450 nm). The overall light attenuation over this region is 33%*, with 65% attenuation over the region from 380 nm to 400 nm, and 21% attenuation over the region from 400 nm to 450 nm. This represents the filtration of the contact lens through the central 6 mm portion for a lens with 0.09 mm center thickness (-3.00 D, thinnest projected parameter). Filtration would increase for contact lens powers with higher center thickness.

Wavelength	Percent integrated attenuation transmittance of high energy visible light*
380 nm to 400 nm	65%
400 nm to 450 nm	21%
380 nm to 450 nm	33%



—— Delefilcon A with light absorbing chromophores: Contact lens with 0.09 mm center thickness measured through central 6 mm portion for the thinnest marketed lens (-3.00 D, thinnest projected parameter).

—— Human Cornea from a 24 year old person as described in Lerman S., Radiant Energy and the Eye, MacMillian, New York, 1980, p.58, Figure 2-21.

—— Human crystalline lens from a 25 year old person as described in Waxler M., Hitchins V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.

---- Combined filtering effect of the contact lens and the natural crystalline lens on retinal exposure.

*Figure 1: **Transmittance of a DAILIES TOTAL1™ for Astigmatism (delefilcon A) Contact Lens versus a Human Cornea and a Human Crystalline Lens***

INDICATIONS (Uses)

DAILIES TOTAL1™ for Astigmatism (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to 6.00 diopters (D) of astigmatism.

The lenses are to be used for single use, daily disposable wear (less than 24 hours while awake) only. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

CONTRAINDICATIONS (Reasons Not to Use)

DO NOT use delefilcon A soft contact lenses when any of the following exists:

- Microbial infection of the eye
- Inflammation or infection of the anterior chamber of the eye
- Any active disease, injury, or abnormality affecting the cornea, conjunctiva, or eyelids that may be exacerbated by contact lens wear
- Inadequate tear film (dry eye) that interferes with contact lens wear
- Reduced corneal sensitivity (corneal hypoesthesia)
- If eyes become red or irritated
- Use of any medication that is contraindicated or interferes with contact lens wear, including certain eye medications
- Any systemic disease which may be exacerbated by or interferes with safe contact lens wear, handling, or care
- Allergic reactions of the ocular surfaces or adnexa that may be caused by or exacerbated by the wearing of contact lenses
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance, or abnormal ocular response to contact lens wear

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their Eye Care Professional's directions and all labeling instructions for proper use of lenses and lens care products. **Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.**
- If a patient experiences eye discomfort, foreign body sensation, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her Eye Care Professional. It is recommended that contact lens wearers see their Eye Care Professional regularly as directed.
- Studies have shown that contact lens wearers who smoke have a greater risk of suffering ulcerative keratitis than among those who are nonsmokers.[2,3]
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical study results[2] have shown that the risk of ulcerative keratitis is greater for daily wear users who wear their lenses overnight (outside the approved indication) compared to those who do not wear them overnight.
- Non-sterile liquids (i.e., tap water, distilled water, homemade saline solution, or saliva) should not be used as a substitute for any component in the lens care process. The use of tap and distilled water has been associated with *Acanthamoeba* keratitis, a corneal infection that is resistant to treatment and cure.

PRECAUTIONS

To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

Special Precautions for the Eye Care Professional

The following patients may not be suitable candidates and/or may experience a higher rate of adverse effects associated with contact lens wear:

- **Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule or follow-up visit schedule.**
- **Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.**
- **Patients with diabetes may have reduced corneal sensitivity. As a result, they are more prone to corneal injury and will not heal as quickly or completely as non-diabetics.**

Note regarding lens designs and parameters:

Due to the small number of patients enrolled in the clinical investigation of lenses, all refractive powers, design configurations, and 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, 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 evaluated on initial dispensing and monitored on an ongoing basis by the prescribing Eye Care Professional.

Note the following precautions during initial dispensing and subsequent visits:

- Fluorescein, a yellow dye, should not be used while the lenses are on the patient's eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in-eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.
- Patients who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Vision requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Before leaving the Eye Care Professional's office, patients should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.

Eye Care Professionals should carefully instruct the patient to take the following care regimen and safety precautions:

Handling Precautions

- Be sure that before leaving the Eye Care Professional's office, the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. Always wash, rinse, and dry hands with a lint-free towel before handling lenses.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Instruction Booklet for DAILIES TOTAL1™ for Astigmatism (delefilcon A) Soft Contact Lenses and any additional instructions provided by the Eye Care Professional.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container.
- Always handle lenses carefully. If a lens is dropped, small particles or fibers may adhere to the lens surface, which can irritate the eye. Replace with a sterile new lens.
- Discard any lens that has become dehydrated or damaged. Replace with a sterile new lens.

Lens Wearing Precautions

- Remove the lenses before sleeping. Never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- Always keep a supply of replacement lenses on hand or have back-up spectacles available, as lenses should not be reused.
- Do not share lenses with anyone as this may spread microorganisms, which could result in serious eye health problems.
- Lenses should be disposed of each day upon removal from the eye.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the ***CARE FOR A STICKING, TORN, DRY, OR DECENTERED LENS*** section. If non-movement of the lens continues, consult your Eye Care Professional immediately.

* See "Note". There is no demonstrated clinical benefit to a 33% reduction in visible light at wavelengths below 450 nm.

- REMOVE THE LENS IMMEDIATELY if your eye becomes red or irritated.
- Promptly remove the lens to avoid serious injury in the event that dust, a foreign body, or other contaminant gets between the lens and the eye.
- Avoid all harmful or irritating vapors and fumes while wearing lenses to reduce the chance of lens contamination or physical trauma to the eye.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products, or foreign particles come in contact with lenses. If sprays are used, eyes should be kept closed until the spray has settled.
- Consult an Eye Care Professional about wearing lenses during water sports and water related activities. Contact lens exposure to non-sterile water during activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection including, but not limited to, *Acanthamoeba* keratitis.
- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
- Do not use lenses beyond the expiration date.

Solution Precautions

- Do not use saliva or any liquid other than the recommended solution for lubricating or rewetting drops with the lenses.

Other Topics to Discuss with Patients

- Periodic eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response. Alcon recommends that patients see their Eye Care Professional at least once each year or as recommended by the Eye Care Professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision, or visional changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using these medications accordingly and prescribe proper remedial measures.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

It is strongly recommended that patients be provided with a copy of the DAILIES TOTAL1™ for Astigmatism (delefilcon A) soft contact lens Patient Instruction Booklet available from Alcon. It is important that patients understand its contents prior to dispensing the lenses.

Who Should Know the Patient is Wearing Contact Lenses

- Instruct patients to inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may prohibit the wearing of contact lenses.
- Instruct the patients to inform their health care professionals that they are wearing contact lenses, as certain medications may interfere with contact lens wear.

WATER ACTIVITIES

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 showering or swimming, discard them and replace with a new pair. Ask the Eye Care Professional for recommendations about wearing lenses during any activity involving water.

ADVERSE EFFECTS (Possible Problems)

Patients should be instructed to check their eyes regularly to make sure they look well, feel comfortable, and vision is clear.

Potentially serious complications are usually accompanied by one or more of the following signs and symptoms:

- Moderate to severe eye pain not relieved by removing the lens
- Feeling of something in the eye (foreign body sensation)
- Excessive watering or other eye secretions, including mucopurulent discharge
- Redness of the eyes
- Sensitivity to light (photophobia)
- Burning, stinging, itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Feeling of dryness

These symptoms, if ignored, may lead to more serious complications.

WHAT TO DO IF A PROBLEM OCCURS

If any of the above signs or symptoms occur:

- IMMEDIATELY REMOVE THE LENSES.
- If the discomfort or problem stops, discard the lens and replace it with a new one.
- If the discomfort or problem continues after removing the lens(es) or upon insertion of a new lens, IMMEDIATELY remove the lens(es) and contact an Eye Care Professional for identification of the problem and prompt treatment to avoid serious eye damage.
- Eye Care Professionals should inform the patient that a serious condition such as corneal ulcer, ulcerative keratitis, infection, corneal vascularization, or iritis may be present. These conditions may progress rapidly and may lead to permanent loss of vision. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated properly to avoid more serious complications.
- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include, but are not limited to, local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection, or iritis.

CARE FOR A STICKING, TORN, DECENTERED, OR DRY LENS

Patients should be informed that it may be possible to resolve less serious problems associated with contact lens wear by following the directions below. However, if following these directions does not resolve the problem, patients should consult their Eye Care Professional immediately to avoid injury to the eye.

- **The lens should move freely on the eye at all times.** If the lens sticks (stops moving) or begins to dry on the eye, apply several drops of a recommended lubricating solution (used in accordance with package labeling). Wait until the lens begins to move freely on the eye before attempting to remove it. It is important that you wash and dry your hands thoroughly before removing the lens. If the lens continues to stick, IMMEDIATELY consult your Eye Care Professional.
- **If a lens tears in your eye**, remove the pieces carefully by pinching them as you would for normal lens removal. If the lens pieces do not seem to remove easily, do not pinch the eye tissue. Rinse with saline. If this does not help, contact the Eye Care Professional for assistance.
- **If a lens decenters on the eye**, it may be possible to re-center it by:
  - Closing your eyelids and gently massaging the lens into place, or
  - Looking in the direction of the lens and blinking gently, or
  - Gently pushing the off-centered lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.
- **Occasional dryness** may be relieved by blinking fully several times or by the use of contact lens rewetting drops that are approved for use with soft contact lenses. If dryness persists, consult your Eye Care Professional.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes:

- Flush eyes immediately with fresh saline solution or tap water.
- Remove and discard lenses and immediately contact the Eye Care Professional or visit a hospital emergency room without delay.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of delefilcon A contact lenses, please notify: **Alcon Medical Affairs in the USA at 1-800-757-9780.**

FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to DAILIES TOTAL1™ for Astigmatism (delefilcon A) contact lenses. For a detailed description of the fitting techniques, refer to the DAILIES TOTAL1™ for Astigmatism (delefilcon A) soft contact lens Professional Fitting and Information Guide for more information. Both the Professional Fitting and Information Guide and a Patient Instruction Booklet are available free of charge from:

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099, USA
or by calling Alcon Customer Service in the USA at:
1-800-241-5999

LENS WEAR AND REPLACEMENT SCHEDULE

Daily Wear (less than 24 hours, while awake)

- Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24-hour period; however, optimum individual wearing schedules will vary.
- The maximum daily wearing time should be determined by the Eye Care Professional based upon the patient's physiological eye condition because individual responses to contact lenses vary.
- Daily wear patients may initially over-wear the lenses. Avoid this tendency by stressing the importance of adhering to a proper initial wearing schedule. For patients who are new to daily wear, gradually increasing scheduled wearing time may allow ocular tissues to more easily adapt to contact lens wear.

Lens Replacement

- Delefilcon A contact lenses are intended to be worn once (daily disposable wear) and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a fresh new lens.

LENS HANDLING INSTRUCTIONS

- Always wash and rinse hands thoroughly and dry completely with a clean, lint -free towel before handling contact lenses.
- Note the correct lens power for each eye to avoid getting them mixed up.
- Do not use if blister package is damaged or not sealed completely. This may result in product contamination, which can lead to a serious eye infection.
- Shake the blister pack (containing a fresh new lens) gently prior to opening.
- Remove the lens from the blister pack by carefully pouring it onto the palm of the hand.
- Ensure that the lens is right side out.
- Inspect the lenses prior to insertion. Do not insert damaged or unclean lenses.

Lens Insertion Instructions

- Wash and rinse hands thoroughly and dry completely with a clean, lint-free towel.
- Place a lens on the tip of your clean and dry right or left index finger. Place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
- Use the fingers of the other hand to lift the upper eyelid.
- Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
- Look down and slowly release the lower lid.
- Look straight ahead and slowly release the upper lid.
- Blink gently.

Lens Removal Instructions

- Wash and rinse hands thoroughly, and dry completely with a clean, lint-free towel.
- Blink fully several times.
- While looking up, use the tip of the finger to slide the lens down onto the white part of the eye.
- Remove the lens by pinching gently between thumb and forefinger. Do not pinch the eye tissue.
- If the lens is difficult to grasp, dry fingers once more and try again. Do not use rewetting drops in this instance.
- Never use tweezers or other sharp objects such as fingernails to remove lenses from your eyes.

LENS CARE DIRECTIONS

- To help avoid serious eye injury from contamination, the Eye Care Professional should review the following instructions with the patient:
- Cleaning and disinfection of daily disposable lenses is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times.
- Do not use saliva, tap water, homemade saline solution, distilled water, or anything other than the recommended rewetting drops or lubricants indicated for use with soft lenses.

DISPOSAL AND RECYCLING

Dispose of contact lenses and the blister pack lidding in the waste bin, not down the toilet or sink. The carton packaging and the polypropylene (PP) plastic shell of the blister pack should be placed in the waste bin or recycled according to local waste management guidance.

IN OFFICE USE OF TRIAL LENSES

Eye Care Professionals should educate contact lens technicians concerning proper use of trial lenses. Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline solution. Hands should be thoroughly washed, rinsed, and dried with a lint-free towel prior to handling a lens. In order to ensure sterility, the blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes, the lenses should be disposed of after a single use and not be re-used from patient to patient.

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic blister pack containing phosphate buffered saline solution with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic) acid and is steam sterilized The package is marked with the base curve, diameter, dioptric power, cylinder axis and power (where applicable), ADD power (where applicable), manufacturing lot number, date of manufacture, and expiration date. Lenses are supplied in cartons containing up to 90 individually sealed contact lenses.

The following may appear on labels or cartons:

Symbol / Abbreviation	Description
BC	Base Curve
DIA	Diameter
PWR	Power
D	Diopter
L	Left
R	Right
CYL AXIS	Cylinder power and axis
UV	Ultra-violet
UVA	Ultra-violet A
UVB	Ultra-violet B
UV-Vis	Ultra-violet and Visible
HEVL	High Energy Visible Light (blue light)
	Packaging waste license sign
	Do not re-use
LOT	Batch code
EXP	Use-by date (Expiry date)
	Single sterile barrier system
STERILE	Sterilized using steam
CE	European conformity mark
en	English (example of two letter code for the language)
	Caution
	Consult instructions for use
	Do not use if blister package is damaged
	DO NOT DISPOSE LENSES IN TOILET OR SINK
	Manufacturer
	Date of manufacture
REF	Medical device
EC REP	Authorized representative in the European Community
Rx only	CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.

Manufacturer:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099, USA

Date: August 2021

U.S. Pat.: www.alconpatents.com

[1] Check for actual product availability which may change over time.
[2] Cutter GR, Chalmers RL, Roseman M. The Clinical Presentation, Prevalence, and Risk Factors of Focal Corneal Infiltrates in Soft Contact Lens Wearers. *The CLAO Journal*. Jan 1996; 22 (1): 30-37.
[3] Schein OD, Glynn RJ, Poggio EC, Seddon JM, Kenyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily-Wear and Extended-Wear Soft Contact Lenses. *The New England Journal of Medicine*. 1989; 321(12):773-783.

Alcon

W900409251-0821

PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR-6576 Evaluation of Lens Rotation in Habitual Wearers of Toric, Soft Contact Lenses

Version and Date: 1.0 03 October 2024

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

I agree to conduct this study according to ISO 14155:2020[1], Declaration of Helsinki[2] , United States (US) Code of Federal Regulations (CFR)[3], and International Council for Harmonization Good Clinical Practice E6(R2) (ICH GCP)[4] and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. I, as the Principal Investigator, am responsible for ensuring that all clinical site personnel, including Sub-Investigators, adhere to all 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 subjects.

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

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.

I have read the suggested guidance provided by JJVCI pertaining to the COVID-19 risk mitigation, (COVID-19 Work Instruction in the Appendix H of this protocol). I agree to conduct this study in compliance with local, state, governmental guidance for COVID-19 risks.

Principal Investigator:

_____ _____
Signature Date

_____
Name and Professional Position (Printed)

Institution/Site: _____
Institution/Site Name

_____
Institution/Site Address