Clinical Study Protocol
Johnson & Johnson Vision Care, Inc.

Clinical Evaluation of Delefilcon A and Verofilcon A Daily Disposable Toric Soft Contact Lenses Over One Week of Wear

Protocol CR-6493

Version: 1.0

Date: 22 July 2022

Investigational Products: Alcon DAILIES TOTAL1® for Astigmatism Daily Contact Lenses, Alcon PRECISION1® for Astigmatism Daily Contact Lenses

Keywords: Astigmatism, Alcon DAILIES TOTAL1® for Astigmatism, Alcon PRECISION1® for Astigmatism, delefilcon A, verofilcon A, daily wear, daily disposable, dispensing, Single use Eye-Cept® Rewetting Drops, LacriPure Saline Solution, ScleralFil Preservative Free Saline Solution, CLUE comfort, CLUE vision, CLUE handling, 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 Clinical investigation of medical devices for human subjects – Good clinical practice[1] and the Declaration of Helsinki.[2]

Confidentiality Statement:

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PROTOCOL TITLE, NUMBER, VERSION AND DATE

Title: Clinical Evaluation of Delefilcon A and Verofilcon A Daily Disposable Toric Soft Contact Lenses Over One Week of Wear
Protocol Number: CR-6493
Version: 1.0
Date: 22 July 2022

SPONSOR NAME AND ADDRESS

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

MEDICAL MONITOR

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 your assigned clinical research associate.

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

AUTHORIZED SIGNATURES

The signatures below constitutes 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 and applicable U.S. federal regulations,[4] ISO 14155:2020,[1] ICH guidelines,[2] and the Declaration of Helsinki.[3]

Author & Study Responsible Clinician	*See Electronic Signature Report* [redacted]	DATE
Clinical Operations Manager	*See Electronic Signature Report* [redacted]	DATE
Biostatistician	*See Electronic Signature Report* [redacted]	DATE
Data Management	*See Electronic Signature Report* [redacted]	DATE
Medical Safety Officer	*See Electronic Signature Report* [redacted]	DATE
Approver	*See Electronic Signature Report* [redacted]	DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Justification for Change	Date
1.0	[redacted]	Original Protocol	N/A	July 22, 2022

SYNOPSIS

Protocol Title	Clinical Evaluation of Delefilcon A and Verofilcon A Daily Disposable Toric Soft Contact Lenses Over One Week of Wear
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Descriptive study phase: Post-market Design control phase: Post-market, phase 4
Trial Registration	This study will be registered on ClinicalTrials.gov by the Sponsor.
Test Article(s)	Approved Products: Test: DAILIES TOTAL1® for Astigmatism Contact Lenses (DT1fA) Control: PRECISION1™ for Astigmatism Contact Lenses (P1fA)
Wear and Replacement Schedules	Wear Schedule: Daily wear Replacement Schedule: Daily disposable
Objectives	Primary Objective: To evaluate the incidence of grade 3 or higher biomicroscopy findings following a 7(±2) day wear period for DAILIES TOTAL1® for Astigmatism Contact Lenses (DT1fA) relative to PRECISION1™ for Astigmatism Contact Lenses (P1fA) as control. Exploratory Objectives: To evaluate the subjective comfort, vision and handling, visual acuity, and rotational performance over a 7(±2) day wear period for DT1fA relative to P1fA as control.

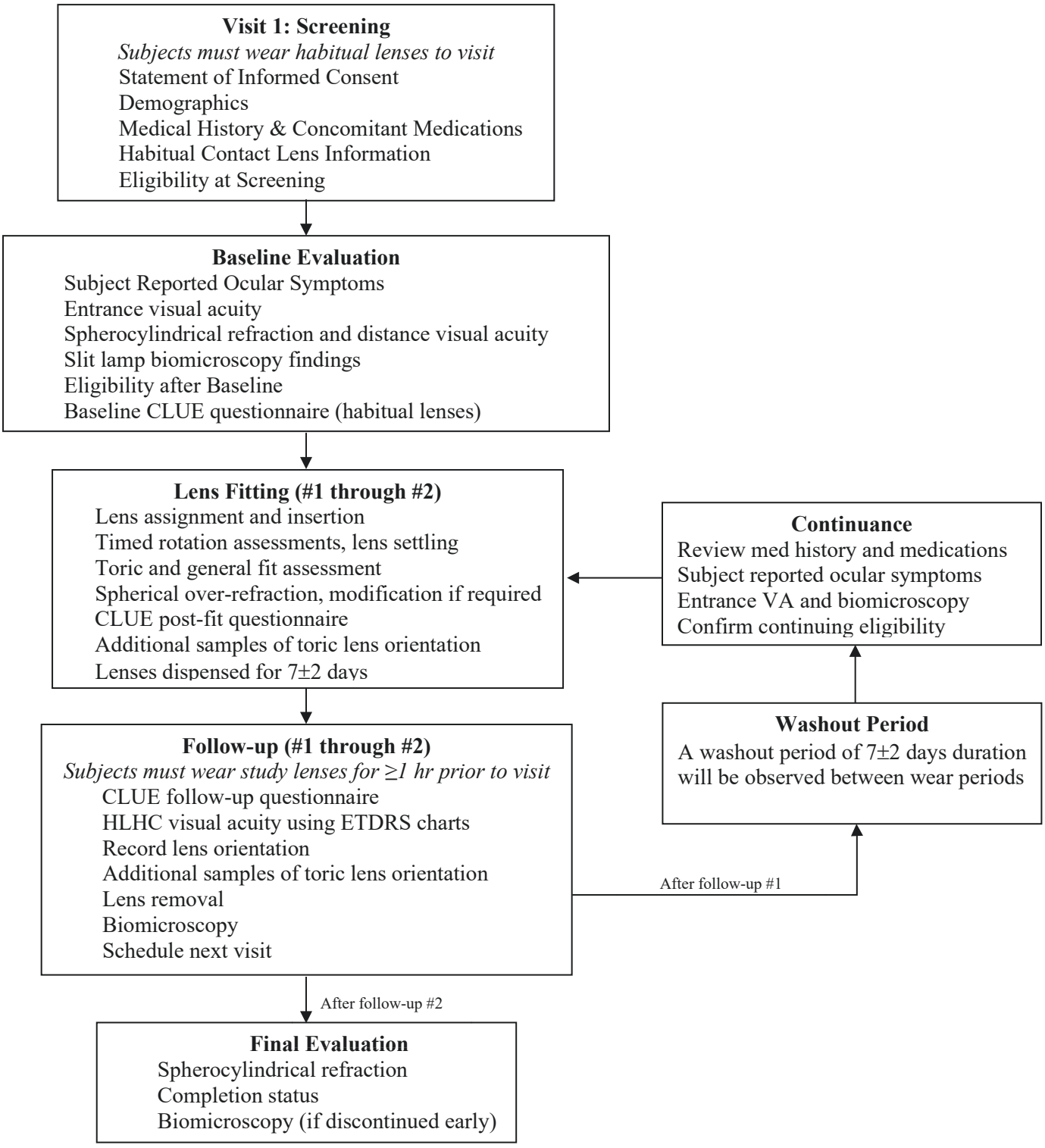
Study Endpoints	Primary endpoint: • Incidence of grade 3 or higher biomicroscopy findings using the FDA grading scale following a 7(±2) day wear period Observational endpoints (efficacy): • Subjective comfort, vision and handling at fitting and following a 7(±2) day wear period using the CLUE questionnaire • High-luminance, high-contrast (HLHC) visual acuity in logMAR measured using ETDRS charts at follow-up • Lens orientation at 1 minute and 3 minutes following insertion at fitting • Mean and standard deviation of settled lens orientation calculated from repeated measures of settled lens orientation at fitting and follow-up visits Observational endpoints (safety): • Adverse events All endpoints will be summarized using descriptive statistics only; no formal hypothesis testing is planned.
Study Design	This is a bilateral, dispensing, randomized, controlled, double masked, 2×2 cross-over study. Each subject will be randomly assigned to one of two wear sequences (test followed by control or control followed by test). Each wear period will be 7(±2) days, with a 7(±2) day washout period between wear periods. There will be a total of 4 visits: Visit 1: Screening, baseline evaluation and lens fit #1 Visit 2: Follow-up evaluation for first lens Visit 3: Continuance, lens fit #2 Visit 4: Follow-up evaluation for second lens See the flow chart at the end of the synopsis table for a schematic of the study visits and procedures (Figure 1).
Sample Size	This study will have an enrollment target of approximately 66 subjects, with a target of at least 60 to complete (assuming a dropout rate of 10%).
Study Duration	Total study duration including the enrollment period is anticipated to be approximately 8 weeks.
Anticipated Study Population	Subjects will be habitual 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 (inclusive) years of age at the time of screening. 4. By self-report, habitually wear soft contact lenses in both eyes in a daily reusable or daily disposable wear modality (i.e., not extended wear modality). Habitual wear is defined as a minimum of 6 hours of wear per day, for a minimum of 2 days per week during the past month. 5. Possess a wearable pair of spectacles that provide correction for distance vision. Inclusion Criteria at Baseline Evaluation The subject must: 6. Have the spherical component of their vertex-corrected distance refraction must be between -0.875 to -4.625 DS (inclusive) in each eye. 7. Have the magnitude of the cylindrical component of their vertex-corrected distance refraction between 0.625 DC and 1.625 DC in both eyes. 8. Have the cylinder axis of their distance refraction between 165° and 15° (i.e., 180±15°, inclusive) or between 75° and 105° (i.e., 90±15°, inclusive) in each eye. 9. Have best corrected monocular distance visual acuity of 20/30 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. Have a history of strabismus or amblyopia. 9. 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. 10. 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: 11. Have clinically significant (grade 3 or higher on the FDA 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). 12. Have fluctuations in vision due to clinically significant dry eye or other ocular conditions.

	13. 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 procedures associated with the observational endpoints for this study will be: - Grading of ocular physiology by slit lamp biomicroscopy using the FDA grading scale - Completion of the CLUE questionnaire at fitting and follow-up - Measurement of HLHC VA using ETDRS charts at follow-up - Measurement of toric lens orientation using a slit lamp biomicroscope
Microbiology or Other Laboratory Testing	Not applicable for this study.
Study Termination	The occurrence of an Unanticipated Adverse Device Effect (UADE) or Serious Adverse Event (SAE) for which a causal relationship to a test article cannot be ruled out, will result in stopping further dispensing investigational product. In the event of a UADE or SAE, the Sponsor Medical Monitor may unmask the treatment regimen of subject(s) and may discuss this with the Principal Investigator before any further subjects are enrolled.
Ancillary Supplies/ Study-Specific Materials	Lens cases, fluorescein strips and preservative-free rewetting drops / artificial tears will be supplied for use as needed.
Principal Investigator(s) and Study Institution(s)/Site(s)	A full list of Principal Investigators, clinical sites, and institutions is kept separately from the Study Protocol and is included in the study Trial Master File.

Figure 1: Study Flowchart



COMMONLY USED ABBREVIATIONS, ACRONYMS AND DEFINITIONS OF TERMS

ADE	Adverse Device Effect
ADHD	Attention Deficit Hyperactivity Disorder
AE	Adverse Event/Adverse Experience
BSCVA	Best Spectacle Corrected Visual Acuity
CFR	Code of Federal Regulations
CLUE	Contact Lens User Experience
COM	Clinical Operations Manager
COVID-19	Coronavirus Disease 2019
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
[redacted]	[redacted]
D	Diopter
DMC	Data Monitoring Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
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	Intent-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
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
VA	Visual Acuity

1. INTRODUCTION AND BACKGROUND

DAILIES TOTAL1® for Astigmatism Contact Lenses (DT1fA) and PRECISION1® (verofilcon A) for Astigmatism Contact Lenses (P1fA) are daily disposable lenses indicated for the correction of astigmatism and associated ametropia in persons with non-diseased eyes. The purpose of this study is to evaluate the ocular physiological response following wear of DT1fA relative to P1fA as control.

1.1. Name and Descriptions of Investigational Products

The test lens in this study will be DT1fA. DT1fA contact lenses are made from a lens material that is 33% water and 67% (delefilcon A) polymer, a silicone containing hydrogel with added phosphatidylcholine. DT1fA lenses also contain a handling tint (color additive copper phthalocyanine).

The control lens in this study will be P1fA. P1fA soft contact lenses are made from a lens material that is 51% water and 49% verofilcon A, a silicone containing hydrogel. The color additive Reactive Blue 247 is added to the lens material to create a light blue edge-to-edge color to make it easier to see when handling. In addition, P1fA lenses contain a benzotriazole UV-absorbing monomer 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 to 380 nm for the entire power range.

Further details about the test articles are found in section 6.1 of this protocol and in the DT1fA and P1fA package inserts (Appendix C).

1.2. Intended Use of Investigational Products

The intended use of the investigational products is the correction of astigmatism and associated myopic refractive error. Study lenses will be worn bilaterally in a daily wear, daily disposable modality for at least 8 hours per day. Each wear period will be 7±2 (i.e., 5 to 9) days in duration, and subjects will be instructed to wear lenses for at least 5 days per week during each wear period. Two wear periods will be completed, with a washout period of 7±2 days between the wear periods.

1.3. Summary of Findings from Nonclinical Studies

Not Applicable – marketed product only.

1.4. Summary of Known Risks and Benefits to Human Subjects

The anticipated clinical benefit of the investigational lenses will be the correction of refractive error. The risks associated with use of the investigational lenses are considered to be equivalent to those associated with other marketed soft contact lenses worn in the same modality (i.e., daily disposable).

Comprehensive risk and benefit information regarding the study lenses are included in the DT1fA and P1fA package inserts (Appendix C).

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

Both DT1fA and P1fA are approved in the US for the correction of astigmatism and associated ametropia in persons with non-diseased eyes.

For further details regarding literature references and prior data relevant to these lenses, refer to the DT1fA and P1fA package inserts (Appendix C).

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

Primary Objective:
To evaluate the incidence of grade 3 or higher biomicroscopy findings following a 7(±2) day wear period for DAILIES TOTAL1® for Astigmatism Contact Lenses (DT1fA) relative to PRECISION1® for Astigmatism Contact Lenses (P1fA) as control.

Exploratory Objectives:
To evaluate the subjective comfort, vision and handling, visual acuity, and rotational performance over a 7(±2) day wear period for DT1fA relative to P1fA as control.

2.2. Endpoints

Primary endpoint:

- Incidence of grade 3 or higher biomicroscopy findings using the FDA grading scale following a 7(±2) day wear period

Observational endpoints (efficacy):

- Subjective comfort, vision, and handling at fitting and following a 7(±2) day wear period using the CLUE questionnaire
- High-luminance, high-contrast (HLHC) visual acuity in logMAR measured using ETDRS charts at follow-up
- Lens orientation at 1 minute and 3 minutes following insertion at fitting
- Mean and standard deviation of settled lens orientation calculated from repeated measures of settled lens orientation at fitting and follow-up visits

Observational endpoints (safety):

- Adverse events

All endpoints will be summarized using descriptive statistics only; no confirmatory hypothesis testing is planned.

2.3. Hypotheses

Not applicable; no confirmatory hypothesis testing for the primary endpoint is planned with respect to data collected in this study. Therefore, any hypothesis testing will be exploratory in nature.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

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

3.2. Inclusion Criteria

Potential subjects must satisfy 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 (inclusive) years of age at the time of screening.
4. By self-report, habitually wear soft contact lenses in both eyes in a daily reusable or daily disposable wear modality (i.e., not extended wear modality). Habitual wear is defined as a minimum of 6 hours of wear per day, for a minimum of 2 days per week during the past month.
5. Possess a wearable pair of spectacles that provide correction for distance vision.

Inclusion Criteria at Baseline Evaluation
The subject must:

6. Have the spherical component of their vertex-corrected distance refraction must be between -0.875 to -4.625 DS (inclusive) in each eye.
7. Have the magnitude of the cylindrical component of their vertex-corrected distance refraction between 0.625 DC and 1.625 DC in both eyes.
8. Have the cylinder axis of their distance refraction between 165° and 15° (i.e., 180±15°, inclusive) or between 75° and 105° (i.e., 90±15°, inclusive) in each eye.
9. Have best corrected monocular distance visual acuity of 20/30 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. Have a history of strabismus or amblyopia.
9. 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.
10. 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:

11. Have clinically significant (grade 3 or higher on the FDA 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).
12. Have fluctuations in vision due to clinically significant dry eye or other ocular conditions.
13. 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.).

3.4. Enrollment Strategy

Study subjects will be recruited from the Institution/clinical site's subject database and/or utilizing Independent Ethics Committee (IEC) or Institutional Review Board (IRB) approved materials.

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This will be a 4-visit, randomized, controlled, double-masked, bilateral wear, dispensing, 2×2 crossover study. Each subject will be randomized into one of two unique sequences to wear two different study lenses one at a time over two wear periods (test followed by control or

control followed by test). During each wear period the lenses will be worn bilaterally for 1 week (7±2 days) in a daily disposable modality. Study lenses will be worn for a minimum of 8 hours per day and at least 5 days per week during the wear period. Subjective comfort, vision, and handling will be assessed using the CLUE questionnaire at both fitting and follow-up visits for each wear period. HLHC VA will be assessed at the follow-up evaluation using ETDRS charts. Ocular health will be assessed by slit lamp biomicroscopy and graded using the FDA grading scale at fitting and follow-up visits. There will be a washout period of 7(±2) days duration between wear periods. Subjects will not have access to the study lenses following completion of the protocol.

4.2. Study Design Rationale

A 2×2 crossover study design was chosen to allow each subject to act as their own active control. A washout period will be included to mitigate any carryover effects.

The prescribed wear schedule (7±2 days, minimum of 8 hours per day, minimum of 5 days per week) was chosen as this is representative of a typical wear schedule for contact lens wearers.

Slit lamp biomicroscopy was selected as the method for assessing ocular health, on the basis that it is the most commonly used instrument for comprehensive examination of the anterior eye. The FDA slit lamp findings classification scale was selected for grading ocular health on the basis that it is widely used and is part of the FDA regulatory guidance for contact lenses (FDA 510(k) guidance).

The investigational lenses will be fitted by optometrists who are experienced at fitting toric soft contact lenses and will be evaluated by habitual contact lens wearers in their standard wearing environment.

4.3. Enrollment Target and Study Duration

This study will have an enrollment target of approximately 66 subjects, with a target of at least 60 to complete. The study will be conducted at up to 5 clinical sites, where the enrollment target for each site will be approximately 14 subjects. A subject will be considered enrolled upon signing of the informed consent form.

There will be 4 visits in total per subject. The total study duration including the enrollment period is expected to be approximately 8 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 that the study data is hard locked.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

This study will be a randomized, double-masked, 2×2 crossover design. Subjects will be randomized into one of 2 unique sequence groups in a 1:1 allocation ratio to wear two different study lens designs (test and control designs) one at a time bilaterally over 2 wear periods.

Use of the test articles will be randomized using a randomization scheme supplied by the study biostatistician. The randomized assignment of subjects will be performed at the first visit prior to the first fitting. Clinical sites 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

Randomly permuted block randomization will be used to avoid bias in the assignment of subjects to treatment and to enhance the validity of statistical comparisons across treatment groups.

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

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

5.2. Masking

To reduce the possibility of bias, this will be a double-masked trial. Subjects will not be aware of the identity of the assigned lenses. The identity of the study lenses will be masked by having the blister packs labeled with the study number, lot number, sphere power, cylinder power, axis, expiration date and randomization code. While clinical trial personnel (including investigators, site technicians, data management, the study biostatistician, and clinical operations personnel) will be aware of the brand and type of lenses included in the study, every attempt will be made to ensure they are not made aware of the corresponding randomization codes for the test and control lenses. Only the unmasked Biostatistician generating the randomization scheme (lens fitting schedule) will have access to the decode information that allows matching of the randomization codes to the investigational articles. The medical monitor will also have access to the decode information in case breaking the mask is necessary for the urgent medical treatment of a subject.

5.3. Procedures for Maintaining and Breaking the Masking

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

Subjects who have had their treatment assignment unmasked are expected to return for all remaining scheduled evaluations. Subjects who are discontinued may be replaced at the discretion of the study sponsor.

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Test	Control
Test Article Form	Soft contact lens	
Brand and Product Name	DAILIES TOTAL1® for Astigmatism	PRECISION1® for Astigmatism
Manufacturer	Alcon Laboratories, Inc.	
Packaging Form	Blister packaging in sterile packing solution	
Packaging Solution	Phosphate buffered saline solution with wetting agents	
Lens Material	delefilcon A	verofilcon A
Sphere Powers (DS)	-1.00 to -4.50 in 0.25 steps	
Cylinder Powers (DC)	-0.75, -1.25	
Cylinder Axes (°)	10, 80, 90, 100, 170, 180	
Nominal Water Content (%)	33%	51%
Nominal Base Curve (mm)	8.6	8.5
Lens Diameter (mm)	14.5	
Fiducial marks	6 o'clock scribe mark	
Dk (intrinsic Dk-Coulometric method, $\times 10^{-11}$ [cm^2 /sec] [ml O_2/ml × mm Hg] at 35°C)	140	90
Modality in Current Study	Daily wear	
Replacement Frequency in Current Study	Daily disposable	
[redacted]	[redacted]	[redacted]

In total, both test and control lenses will be available in 180 unique lens powers (15 sphere powers × 2 cylinder powers × 6 axes).

The total number of test lenses to be used in this study (not including lenses that are replaced due to droppage, loss or damage) is expected to be approximately 924 lenses (target enrollment of 66 subjects × 2 eyes per subject × 7 day wear period). Test and control lenses will be worn in a 1:1 ratio, thus the number of control lenses to be used is expected to be approximately the same (924 lenses).

6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 2: Ancillary Supplies

	Non-Preserved Rewetting Drops		
Solution Name/Description	Single use Eye-Cept® Rewetting Drops	LacriPure Saline Solution	ScleralFil Preservative Free Saline Solution
Manufacturer	Optics Laboratory	Menicon	Bausch & Lomb
Preservative	None	None	None

Lens cases and fluorescein strips (either 0.6 mg or 1.0 mg) will be supplied for use as needed.

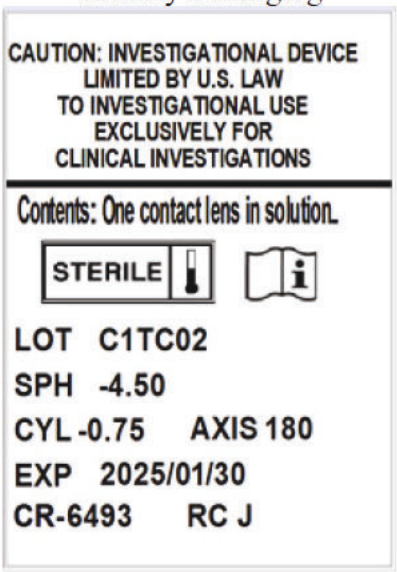
6.3. Administration of Test Articles

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

6.4. Packaging and Labeling

The test articles will be supplied in blister packages as the primary packaging and placed into plastic bags as secondary packaging. Test and control blister packages will be physically over-labeled with permanent labels. Representative sample labels for the primary and secondary packaging are shown below:

Primary Packaging



Secondary Packaging

6.5. Storage Conditions

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

6.6. Collection and Storage of Samples

No samples will be collected as part of the study procedures. When possible, any lens or test article associated with an Adverse Event and/or a Product Quality Complaint must be retained and stored in a glass vial with moderate solution pending directions from the sponsor for potential return to JJVC.

6.7. Accountability of Test Articles

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

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

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

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

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

[redacted]

7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 3: Time and Events

Visit Information	Visit 1 Screening, Baseline, Lens Fitting #1	Visit 2 Follow-up #1	Visit 3 Continuance, Lens Fitting #2	Visit 4 Follow-up #2, Final Evaluation
Time Point	Day 0	7 ± 2 days following Visit 1	7 ± 2 days following Visit 2	7 ± 2 days following Visit 3
Minimum lens wear time immediately prior to visit	Must wear habitual lenses	1 hour (study lenses)	No requirement for this visit	1 hour (study lenses)
Estimated Visit Duration	2.5 hours	1.5 hours	1.5 hours	1.5 hours
Statement of informed consent	x			
Demographics	x			
Medical history/concomitant medications	x	x	x	x
Habitual contact lens information	x			
Habitual lens wear time	x			
Eligibility at Screening	x			
Subject reported ocular symptoms	x	x	x	x
Baseline PRO questionnaire	x			
Entrance visual acuity	x	x	x	x
Remove habitual lenses	x		x	
Subjective Sphero-Cylindrical Refraction	x			x
Slit Lamp Biomicroscopy	x	x	x	x
Eligibility at Baseline	x			
Lens Selection	x		x	
Lens insertion and timed rotation assessments	x		x	
Lens settling	x		x	
Toric fit assessment	x		x	
General fit assessment	x		x	
Spherical over-refraction	x		x	
Lens modification (if necessary)	x		x	
Post-fit PRO questionnaire	x		x	
Additional samples of toric lens orientation (performed twice)	x	x	x	x
Exit visual acuity	x	x	x	
Dispensing criteria	x		x	
Dispensing instructions	x		x	
Schedule next visit	x	x	x	

Visit Information	Visit 1 Screening, Baseline, Lens Fitting #1	Visit 2 Follow-up #1	Visit 3 Continuance, Lens Fitting #2	Visit 4 Follow-up #2, Final Evaluation
Time Point	Day 0	7 ± 2 days following Visit 1	7 ± 2 days following Visit 2	7 ± 2 days following Visit 3
Minimum lens wear time immediately prior to visit	Must wear habitual lenses	1 hour (study lenses)	No requirement for this visit	1 hour (study lenses)
Estimated Visit Duration	2.5 hours	1.5 hours	1.5 hours	1.5 hours
Wear time and compliance		x		x
Collect unworn lenses		x		x
Follow-up PRO questionnaire		x		x
Distance HLHC visual acuity using ETDRS charts		x		x
Toric lens orientation		x		x
Lens removal		x		x
Continuance			x	
Subject completion status				x

7.2. Detailed Study Procedures

VISIT 1

Subjects must wear their habitual contact lenses to this visit.

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the consent form. **Note:** The subject must be provided a signed copy of this document.	
1.2	Demographics	Record the subject's year of birth, age, gender, race and ethnicity.	
1.3	Medical History and Concomitant Medications	Record the subject's medical history and concomitant medications.	
1.4	Habitual Lenses	Record the subject's habitual lens type, parameters, lens care solution, wear modality, and approximate prescription date.	

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.5	Habitual lens wear time.	Record the average and comfortable wear time for the subject's habitual contact lenses.	
1.6	Eligibility after Screening	All responses to Screening Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible. *If subject is deemed to be ineligible after screening, proceed to Final Evaluation and complete Subject Disposition. Refraction and Biomicroscopy forms do not need to be completed as part of Final Evaluation.*	

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.7	Subject reported ocular symptoms	Record any subject reported ocular symptoms reported with regard to their habitual contact lenses.	
1.8	Baseline PRO questionnaire	Ask the subject to fill out the baseline questionnaire regarding their experience with their **habitual contact lenses**.	
1.9	Entrance visual acuity	Record the monocular distance Snellen visual acuity for each eye (OD, OS) to the nearest letter with the subject's habitual contact lens correction. Subjects must continue until at least 50% of the letters on a line are read incorrectly.	
1.10	Remove habitual lenses	The subject's habitual contact lenses will be removed and stored in a lens case, if required.	
1.11	Subjective sphero-cylindrical refraction	Conduct a full spherocylindrical bare eye subjective refraction with binocular balance and record the resultant monocular visual acuity for each eye to the nearest letter. *Note: The duo-chrome test should be used for refining the monocular and binocular spherical endpoints. This test will be considered to have reached the endpoint when the targets on red and green backgrounds appear to be equally sharp. However, if the subject's response changes immediately from "red" to "green" with a 0.25DS change in power, the endpoint will be the most plus power (with "red" target clearer) before this reversal.*	

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.12	Slit lamp biomicroscopy	The FDA Slit Lamp Classification Scale will be used to grade findings. If any slit lamp finding is graded as 3 or worse, the visit will be discontinued; however, the subject may repeat the baseline evaluation (one time) at a later date once the condition lessens. Should the clearance of the fluorescein need to be expedited, preservative-free rewetting drops or artificial tears may be instilled.	
1.13	Eligibility at baseline	All responses to Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible. If subject is deemed to be ineligible after baseline, proceed to Final Evaluation.	

Visit 1: Lens Fitting #1			
Step	Procedure	Details	[redacted]
1.14	Lens selection	Assign the study lens based on the randomization scheme. Select the fitting lens powers based on vertex-corrected subjective refraction for each eye, with consideration of the following guidelines: 1. Label cylinder axis should be determined by rounding the refraction cylinder axis to the nearest 10 degrees. Axis ending in the digit '5' should be rounded towards 180 for eyes with with-the-rule astigmatism, or towards 90 for eyes with against-the-rule astigmatism (e.g., 175 should be rounded to 180, 105 should be rounded to 100). 2. Cylinder power should be chosen based on the following table:	

Vertex corrected cylinder power (X) within the range: (DC)	Label cylinder power to be fit (DC)
$-0.625 \leq X < -1.125$	-0.75
$-1.125 \leq X < -1.625$	-1.25

		3. The fitting lens spherical equivalent (SE) power (label sphere power + 1/2 of the label cylinder power) should be as close as possible to the SE of the vertex-corrected refraction. If	

Visit 1: Lens Fitting #1			
Step	Procedure	Details	[redacted]
		the SE of the vertex-corrected refraction is exactly halfway between two label SE powers, the least minus label power should be fit first.	
1.15	Right eye lens insertion	Instruct the subject to insert the right-eye lens with random orientation. If lens is uncomfortable, inspect for damage and remove, reinsert, or replace as necessary.	[redacted]
1.16	Timed rotation assessments during settling period	Start a stopwatch (or suitable smartphone or tablet timing app) as soon as the right lens is inserted. Record lens rotation (direction and magnitude) to the nearest degree at one (1) and three (3) minutes following insertion. *Note: All lenses in this study have scribe marks at the 6 o'clock position and rotation measurements are made relative to a vertical reference line.*	
1.17	Left eye lens insertion	Instruct the subject to insert the left-eye lens with random orientation. If lens is uncomfortable, inspect for damage and remove, reinsert, or replace as necessary.	[redacted]
1.18	Timed rotation assessments during settling period	Start a stopwatch (or suitable smartphone or tablet timing app) as soon as the left lens is inserted. Record lens rotation (direction and magnitude) to the nearest degree at one (1) and three (3) minutes following insertion. *Note: All lenses in this study have scribe marks at the 6 o'clock position and rotation measurements are made relative to a vertical reference line.*	
1.19	Lens settling	Allow lenses to settle for a period of at least 15 minutes following left lens insertion.	
1.20	Toric fit assessment	Record for each eye: 1. The rotational position to the nearest degree 2. Lens stability with blinks 3. Toric fit acceptability. The toric lens fit will be designated as 'unacceptable' if either: a. The lens ABSOLUTE ROTATION is greater than 20 degrees b. The LENS STABILITY WITH BLINK is greater than 5 degrees If one or both lenses demonstrate an unacceptable toric fit, the subject will be discontinued (proceed to final evaluation).	[redacted]

Visit 1: Lens Fitting #1			
Step	Procedure	Details	[redacted]
1.21	General lens fit assessment	The fitting characteristics of the lens in both eyes will be assessed using a slit lamp. Lens position (centration, limbal exposure, edge lift) and movement (primary and up gaze as well as push-up) will be assessed. Fit acceptability is defined as any lens that does **not** display the following general fit characteristics: • Limbal exposure (presence of clear cornea) in any direction of gaze. • Edge lift. • Insufficient movement in all three movement assessments (primary gaze, up-gaze and push-up test). • Excessive movement in primary gaze. If the general fit is unacceptable for either eye, the subject will be discontinued (proceed to exit evaluation).	[redacted]
1.22	Spherical over-refraction	Perform monocular spherical over-refraction using duo-chrome to refine the endpoint as described in step 1.11 (the final spherical endpoint may be determined binocularly). **The spherical over-refraction must be plano in both eyes to continue**. If a non-plano over-refraction is found in either eye, the **lens(es) must be refit with the indicated change in sphere power**. If the indicated lens power is not available for either eye (e.g., outside the available SKU range), the subject will be discontinued (proceed to final evaluation).	[redacted]
1.23	Lens modification (if necessary)	If modification is necessary in one or both eyes, select the reason for refitting lenses: • The settled lens rotation is such that a different cylinder axis would be more appropriate (use the LARS rule to determine the replacement lens cylinder axis) • The spherical over-refraction is not plano • Other (specify reason) Repeat steps 1.15 through 1.22 for one or both eyes, as appropriate. A maximum of 2 lens modifications are allowed per eye. If, for either eye, the fit is not successful after 2 modifications, the subject will be discontinued (proceed to final evaluation).	

Visit 1: Lens Fitting #1			
Step	Procedure	Details	[redacted]
1.24	Post-fit PRO questionnaire	Subjects will complete a PRO questionnaire regarding the initial comfort, vision and handling of the study lenses.	
1.25	Additional sample of toric lens orientation (1)	Instruct the subject to leave the consulting room and walk around for at least 2 minutes. Upon their return, measure and record the toric lens orientation for each eye **to the nearest degree**.	
1.26	Additional sample of toric lens orientation (2)	Repeat the previous step once again.	
1.27	Exit visual acuity	Record the exit monocular distance Snellen visual acuity for each eye with the subject wearing the study lenses.	
1.28	Dispensing criteria	Lenses may be dispensed if both following conditions are met: 1. The monocular distance visual acuity with the study lenses is equal to or better than 20/25 in each eye. 2. The subject indicates that the comfort and vision with the study lenses is acceptable. If either of these conditions is not met, the subject will be discontinued (proceed to exit evaluation).	
1.29	Dispensing instructions	If the study lenses are suitable for dispensing: • Instruct the subject to wear the study lenses for at least 8 hours per day (in a daily wear / daily disposable modality) on at least 5 days of the wear period. **Subjects must not wear their habitual lenses at any time during the dispensing period**. • Provide the subject with a copy of the Patient Instruction Guide. • Preservative-free rewetting drops are permitted, if needed. • Dispense enough lenses for the subject to complete the wear period (i.e., up to and including their scheduled follow-up visit). At the investigator's discretion, in instances where there is a high likelihood of the subject needing replacement lenses (e.g., due to subject activities, unavailability of subject or site during the wear period, high likelihood of lens tears, etc.), one additional spare pair may be dispensed. **Note:** In the event that a subject requires additional lenses due to loss or damage, they may	

Visit 1: Lens Fitting #1			
Step	Procedure	Details	[redacted]
		return to the clinical site for lens replacement. As much as reasonably possible, damaged lenses and packaging should be returned to the clinical site (in solution, if possible) for shipping to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form, store the lens in a labeled vial with saline and return it to the Sponsor. • Ensure the subject is aware of the correct lens power for each eye (label the lenses with R and L as appropriate). • Instruct the subject to bring their habitual spectacles or contact lenses to the next visit (to wear following removal of the study lenses).	
1.30	Schedule next visit	Schedule the follow-up visit to occur in 7 (± 2) days (counting the day of this visit as day 0, the subject may return on day 5 through 9). Ensure the subject is instructed to wear the study lenses for at least 1 hour immediately prior to attending the follow-up visit.	

VISIT 2

Visit 2 will occur 5 to 9 days following Visit 1. Subjects must present to this visit wearing the study lenses in both eyes, and lenses must have been worn for at least 1 hour prior to the visit. Subjects should bring their own habitual spectacles or contact lenses to this visit to wear following study lens removal.

Visit 2: Follow-up #1			
Step	Procedure	Details	[redacted]
2.1	Wear time and compliance	Record the subjects wearing time and comfortable wearing time. Subjects must have worn lenses for at least 8 hours on at least 5 days during the dispensing period, and for at least 1 hour prior to attending this visit.	
2.2	Collect unworn lenses	Collect any unworn study lenses that were dispensed at the previous visit.	
2.3	Review medical history and concomitant medications	Record any changes to the subject's medical history (including adverse events) or concomitant medications.	
2.4	Subject reported ocular symptoms	Record any subject reported ocular symptoms in response to a verbal open-ended symptoms questionnaire.	[redacted]

<table>
<tr><th colspan="4">Visit 2: Follow-up #1</th></tr>
<tr><th>Step</th><th>Procedure</th><th>Details</th><th>[redacted]</th></tr>
<tr><td>2.5</td><td>Follow-up PRO questionnaire</td><td>Subjects will complete a PRO questionnaire to assess their experience with the study lenses.</td><td>[redacted]</td></tr>
<tr><td>2.6</td><td>Entrance visual acuity</td><td>Record the entrance Snellen VA for each eye while wearing the study lenses.</td><td>[redacted]</td></tr>
<tr><td>2.7</td><td>Distance ETDRS visual acuity</td><td>Measure monocular distance high luminance high contrast (HLHC) visual acuity using ETDRS charts at 4 meters.
Measure each eye using the charts shown in the table below:
<table>
<tr><td>Condition</td><td colspan="2">HLHC</td></tr>
<tr><td>Room illumination</td><td colspan="2">> 400 lux</td></tr>
<tr><td>Chart luminance</td><td colspan="2">120 - 200 cd/m^2</td></tr>
<tr><td>Eye</td><td>OD</td><td>OS</td></tr>
<tr><td>Charts</td><td>HC-1
HC-2</td><td>HC-3
HC-4</td></tr>
</table>
Recorded letter-by-letter results into EDC.</td><td>[redacted]</td></tr>
<tr><td>2.8</td><td>Toric lens orientation</td><td>Record the toric lens orientation for each eye to the nearest degree.</td><td></td></tr>
<tr><td>2.9</td><td>Additional sample of toric lens orientation (1)</td><td>Instruct the subject to leave the consulting room and walk around for at least 2 minutes. Upon their return, measure and record the toric lens orientation to the nearest degree in each eye.</td><td></td></tr>
<tr><td>2.10</td><td>Additional sample of toric lens orientation (2)</td><td>Repeat the previous step once again.</td><td></td></tr>
<tr><td>2.11</td><td>Lens removal</td><td>Remove and place both lenses into a lens case with saline solution.
Do not discard the lenses until after biomicroscopy has been completed.</td><td>[redacted]</td></tr>
<tr><td>2.12</td><td>Biomicroscopy</td><td>The FDA Slit Lamp Classification Scale will be used to grade findings. If any slit lamp finding is graded as 3 or worse, the subject must be discontinued, an adverse event will be recorded, and the subject will be monitored as per the guidelines given in section 13.
Should the clearance of the fluorescein need to be expedited, preservative-free rewetting drops or artificial tears may be instilled.
Study lenses may be discarded if there is no reason to store them following biomicroscopy.</td><td>[redacted]</td></tr>
<tr><td>2.13</td><td>Exit visual acuity</td><td>Record the exit monocular distance Snellen visual acuity for each eye with the subject wearing their habitual correction.</td><td>[redacted]</td></tr>
</table>

Visit 2: Follow-up #1			
Step	Procedure	Details	[redacted]
2.14	Schedule next visit	Schedule the next visit (Visit 3) to occur following a washout period of 7(±2) days (counting the day of this visit as day 0, the subject may return on day 5 through 9). Subjects may wear their habitual lenses during the washout period.	

VISIT 3

Visit 3 will occur 5 to 9 days following Visit 2. Subjects may wear their habitual contact lenses to this visit.

Visit 3: Continuance			
Step	Procedure	Details	[redacted]
3.1	Review medical history and concomitant medications	Record any changes to the subject's medical history or concomitant medications.	
3.2	Subject reported ocular symptoms	Record any subject reported ocular symptoms in response to a verbal open-ended symptoms questionnaire.	[redacted]
3.3	Entrance visual acuity	Record the entrance distance Snellen visual acuity for OD and OS with the subject wearing their habitual correction.	[redacted]
3.4	Remove habitual lenses (if worn)	If worn, the subject's habitual contact lenses will be removed. Lenses may be stored in a lens case, if required.	
3.5	Biomicroscopy	The FDA Slit Lamp Classification Scale will be used to grade findings. If any slit lamp finding is graded as 3 or worse, the subject must be discontinued, an adverse event will be recorded and the subject will be monitored as per the guidelines given in section 13. Should the clearance of the fluorescein need to be expedited, preservative free rewetting drops or artificial tears may be instilled.	[redacted]
3.6	Continuance	Verify that the subject is eligible to continue in the study.	

Visit 3: Lens Fitting #2

The steps followed will be the same as those listed under Visit 1: Lens fitting #1.

VISIT 4

Visit 4 will occur 5 to 9 days following Visit 3. Subjects must present to this visit wearing the study lenses in both eyes, and lenses must have been worn for at least 1 hour prior to the visit. Subjects should bring their own habitual spectacles or contact lenses to this visit to wear following study lens removal.

<table>
<tr><th colspan="4">Visit 4: Follow-Up #2</th></tr>
<tr><th>Step</th><th>Procedure</th><th>Details</th><th>[redacted]</th></tr>
<tr><td>4.1</td><td>Wear time and compliance</td><td>Record the subject's wearing time and comfortable wearing time. Subjects must have worn lenses for at least five continuous 8-hour periods during the dispensing period and for at least 1 hour prior to attending this visit.</td><td></td></tr>
<tr><td>4.2</td><td>Collect unworn lenses</td><td>Collect any unworn study lenses that were dispensed at the previous visit.</td><td></td></tr>
<tr><td>4.3</td><td>Review medical history and concomitant medications</td><td>Record any changes to the subject's medical history (including adverse events) or concomitant medications.</td><td></td></tr>
<tr><td>4.4</td><td>Subject reported ocular symptoms</td><td>Record any subject reported ocular symptoms in response to a verbal open-ended symptoms questionnaire.</td><td>[redacted]</td></tr>
<tr><td>4.5</td><td>Follow-up PRO questionnaire</td><td>Subjects will complete a PRO questionnaire to assess their experience with the study lenses.</td><td>[redacted]</td></tr>
<tr><td>4.6</td><td>Entrance visual acuity</td><td>Record the entrance Snellen VA for each eye while wearing the study lenses.</td><td>[redacted]</td></tr>
<tr><td>4.7</td><td>Distance ETDRS visual acuity</td><td>Measure monocular distance high luminance high contrast (HLHC) visual acuity using ETDRS charts at 4 meters.
Measure each eye using the charts shown in the table below:
<table>
<tr><td>Condition</td><td colspan="2">HLHC</td></tr>
<tr><td>Room illumination</td><td colspan="2">> 400 lux</td></tr>
<tr><td>Chart luminance</td><td colspan="2">120 - 200 cd/m^2</td></tr>
<tr><td>Eye</td><td>OD</td><td>OS</td></tr>
<tr><td>Charts</td><td>HC-1
HC-2</td><td>HC-3
HC-4</td></tr>
</table>
Recorded letter-by-letter results into EDC.</td><td>[redacted]</td></tr>
<tr><td>4.8</td><td>Toric lens orientation</td><td>Record the toric lens orientation for each eye to the nearest degree.</td><td></td></tr>
</table>

Visit 4: Follow-Up #2			
Step	Procedure	Details	[redacted]
4.9	Additional sample of toric lens orientation (1)	Instruct the subject to leave the consulting room and walk around for at least 2 minutes. Upon their return, measure and record the toric lens orientation **to the nearest degree** in each eye.	
4.10	Additional sample of toric lens orientation (2)	Repeat the previous step once again.	
4.11	Lens removal	Remove and place both lenses into a lens case with saline solution. *Do not discard the lenses until after biomicroscopy has been completed.*	[redacted]
4.12	Biomicroscopy	The FDA Slit Lamp Classification Scale will be used to grade findings. If any slit lamp finding is graded as 3 or worse, an adverse event will be recorded, and the subject will be monitored as per the guidelines given in section 13. Should the clearance of the fluorescein need to be expedited, preservative free rewetting drops or artificial tears may be instilled. Study lenses may be discarded if there is no reason to store them following biomicroscopy.	[redacted]

FINAL EVALUATION

The final evaluation will ordinarily take place immediately following the last scheduled follow-up visit per the study protocol. It may also take place at any point the subject discontinues the study or is terminated from the study.

Final Evaluation			
Step	Procedure	Details	[redacted]
F.1	Subject Disposition	Indicate if the subject completed the study successfully. If the subject is discontinued from the study, indicate the reason.	
F.2	Exit Refraction	Perform bare-eye subjective spherocylindrical refraction with a phoropter and record the best-corrected distance visual acuity (OD and OS) to the nearest letter. **Note**: This step is not necessary if the subject was exited due to screen failure.	[redacted]

Final Evaluation			
Step	Procedure	Details	[redacted]
F.3	Exit Slit Lamp Biomicroscopy (for subjects that are discontinued early)	FDA Slit Lamp Classification Scale will be used to grade the findings. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops or saline may be instilled. This step is not necessary if the subject was exited due to screen failure. **Note**: This step is not necessary if the subject was exited due to screen failure, or if biomicroscopy was performed as part of the final follow-up visit procedures (i.e., immediately prior to the final evaluation).	

7.3. Unscheduled Visits

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

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

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

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

The following information will be collected during an unscheduled visit.

Unscheduled Visit			
Step	Procedure	Details	[redacted]
U.1	Reason for unscheduled visit	Indicate if the only reason for the visit is that the subject requires additional test articles. If the reason is other than resupply of previously dispensed lenses, specify the reason for the visit.	

Unscheduled Visit			
Step	Procedure	Details	[redacted]
U.2	Chief Complaints (if applicable)	Record the subject's chief complaints for reasons for the unscheduled visit.	
U.3	Adverse Events and Concomitant Medications Review (if applicable)	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
U.4	Entrance VA (if applicable)	Record the entrance distance visual acuity (OD, OS) to the nearest letter.	[redacted]
U.5	Subjective Sphero-cylindrical Refraction (if applicable)	Perform bare-eye subjective spherocylindrical refraction with a phoropter (adopt the maximum plus to maximum visual acuity (MPMVA) approach and use the duo-chrome test for binocular balancing) and record the best corrected distance visual acuity to the nearest letter (OD, OS).	[redacted]
U.6	Slit Lamp Biomicroscopy (if applicable)	FDA Slit Lamp Classification Scale will be used to grade the findings. If the clearance of the fluorescein needs to be expedited, preservative-free rewetting drops may be instilled.	[redacted]
U.7	Dispensing (if applicable)	If the subject requires additional lenses to complete the wear period and is eligible to do so, provide additional lenses per the dispensing instructions given in the detailed study procedures.	
U.8	Exit Visual Acuity (if applicable)	Record the subject's exit distance visual acuity (OD, OS) to the nearest letter.	[redacted]

NOTE: If the only reason for the unscheduled visit is that the subject requires additional test articles, only the dispensing information needs to be recorded.

7.4. Laboratory Procedures

Not applicable.

8. SUBJECTS COMPLETION/WITHDRAWAL

8.1. Completion Criteria

Subjects are considered to have completed the study if they:

- provided informed consent.
- they are eligible.
- have not withdrawn/discontinued from the study for any reason described in section 8.2.

- completed all visits through the final visit (visit 4).
- If all visits were completed but an additional visit is considered necessary for subject care, follow the requirements for unscheduled visits in section 7.3.

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 misses 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 Table 4. 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 Table 4 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, artrial fibrillation, andrenal 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 Table 5. 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, Benedryl, 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, the IEC/IRB.

If the deviation potentially impacts the safety of patient 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 patient safety or technical integrity of the study. They are often logistical in nature.

Protocol waivers are prohibited.

Table 6 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	Visit attended > 3 days out of visit window defined in study procedures	Visit attended ≤ 3 days out of visit window defined in study procedures
Unanswered PRO questions	If questionnaire is not completed (i.e., all questions are unanswered) for any visit.	Any individual PRO questions are unanswered (i.e., left blank).
Insufficient wear of study lenses	Subject does not wear study lenses for at least 8 hours on at least 5 days of a study lens wear period. Subject wears their habitual lenses during any of the study lens wear periods.	Subject does not wear study lenses for at least 1 hour prior to attending a follow-up visit.

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.

11. STUDY TERMINATION

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

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

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

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

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

12. PROCEDURE FOR HANDLING PRODUCT QUALITY COMPLAINTS

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

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

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

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

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

- Date the complaint was received/recorded in the EDC System (Date of Sponsor Awareness).
- Who received the complaint.
- Study number.
- Clinical site information (contact name, site ID, telephone number).
- Lot number(s).
- Unique Subject Identifier(s).
- Indication of who first observed complaint (site personnel or subject).
- OD/OS indication, along with whether 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."
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
- 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.[1]

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.

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 - see definition in section 13.2.1).
- Adverse Event Severity – Adverse event severity is used to assess the degree of intensity of the adverse event (mild, moderate, or severe - see definition in section 0).
- 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.

13.2.1. Causality Assessment

Causality Assessment – A determination of the relationship between an adverse event and the test article. The test article 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.

13.2.2. Severity Assessment

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

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

13.3. Documentation and Follow-Up of Adverse Events

The recording and documenting of adverse events (ocular and non-ocular) 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 patient 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 e-mail, facsimile, or telephone as soon as possible and no later than 24 hours from discovery for any serious /significant adverse events, and 2 days from discovery for any non-significant adverse event. In addition, a written report will be submitted by the Principal Investigator to the IEC/IRB according to their requirements (section 13.4.2). The report will comment whether the adverse event was considered to be related to the test article, study treatment or study procedures.

13.4.1. Reporting Adverse Events to Sponsor

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

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

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

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

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

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

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

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

Adverse events that meet the IEC/IRB requirements for reporting must be reported within the IEC/IRB's written guidelines. Each clinical site will refer to and follow any guidelines set forth by their Approving IEC/IRB. Each clinical site will refer to and follow any guidelines set forth by their local governing Health Authorities.

The Sponsor will report applicable Adverse Events to the local health authorities according 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 participants and their fetuses will not be monitored for study related purposes. Pregnant participants are not discontinued from contact lens or solution related studies for safety concerns, but due to general concerns relating to pregnancy and contact lens use. Specifically, pregnant women are discontinued due to fluctuations in refractive error and/or visual acuity that occur secondary to systemic hormonal changes, and not due to unforeseen health risks to the mother or fetus.

14. STATISTICAL METHODS

14.1. General Considerations

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.

All data summaries and statistical analyses will be performed using the SAS software Version 9.4 or higher (SAS Institute, Cary, NC).[5] Throughout the analysis of data, the results for each subject/eye will be used when available for summarization and statistical analysis.

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

14.2. Sample Size Justification

Approximately 66 subjects will be enrolled in this study to attain a minimum of 60 completed subjects. All endpoints will be summarized using descriptive statistics only; no confirmatory hypotheses will be tested. This is a descriptive study to evaluate the clinical performance of the DT1fA and P1fA lenses. Sample size is not based on the empirical power analysis. The data collected for this study may be used for designing future studies if applicable.

14.3. Analysis Populations

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

Per-Protocol Population:
All subjects who 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.

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

14.4. Level of Statistical Significance

No confirmatory hypothesis testing is planned for this study; hence, the level of statistical significance is not applicable. All planned analyses for this study will be descriptive.

14.5. Primary Analysis

Descriptive summary tables by Lens Type (DT1fA vs. P1fA) for the following safety and efficacy endpoints will be provided.

- Incidence of grade 3 or higher biomicroscopy findings using the FDA grading scale following a 7(±2) day wear period

14.6. *2.30*Secondary Analysis

Not applicable.

14.7. Other Exploratory Analysis

Descriptive summary tables by Lens Type (DT1fA vs. P1fA) for the following exploratory endpoints will be provided:

- Subjective comfort, vision, and handling at fitting and following a 7(±2) day wear period using the CLUE questionnaire
- High-luminance, high-contrast (HLHC) visual acuity in logMAR measured using ETDRS charts at follow-up
- Lens orientation at 1 minute and 3 minutes following insertion at fitting
- Mean and standard deviation of settled lens orientation calculated from repeated measures of settled lens orientation at fitting and follow-up visits

Other exploratory analyses will be determined after reviewing the descriptive summary at the discretion of the study responsible clinician and project team. They may be performed on study endpoints between lens type (DT1fA vs. P1fA) or on endpoints collected in previous JJVC-sponsored studies to generate hypotheses for future confirmatory studies.

14.8. Interim Analysis

Not applicable.

14.9. Procedure for Handling Missing Data and Drop-Outs

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

14.10. Procedure for Reporting Deviations from Statistical Plan

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

15. DATA HANDLING AND RECORD KEEPING/ARCHIVING

15.1. Electronic Case Report Form/Data Collection

The data for this study will be captured on electronic case report forms (eCRFs) using the BioClinica 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.

No external data sources will be included in this study.

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 articles 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, section 4 of the ICH E6(R2) guidelines on Good Clinical Practice (GCP),[2] 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[3] and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with section 8 of the ICH E6(R2) guidelines on Good Clinical Practice (GCP),[2] and applicable regulatory requirements.

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

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

- Final protocol.

- 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,[3] current ICH GCP[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 subject the aims, methods, reasonably anticipated benefits, and potential hazards of the study, and any discomfort it may entail. Subjects will be informed that their participation is voluntary and that they may withdraw consent to participate at any time.

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

18.5. Privacy of Personal Data

The collection, processing and disclosure of personal data and medical information related to the Study Subject, and personal data related to Principal Investigator and any clinical site personnel (e.g., name, clinic address and phone number, curriculum vitae) is subject to compliance with the Health Information Portability and Accountability Act (HIPAA)[6] and other applicable personal data protection and security laws and regulations. Appropriate measures will be employed to safeguard these data, to maintain the confidentiality of the person’s related health and medical information, to properly inform the concerned persons about the collection and processing of their personal data, to grant them reasonable access to their personal data and to prevent access by unauthorized persons.

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

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

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

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

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

The subject has the right to request through the Investigator access to his personal data and the right to request rectification of any data that are not correct or complete. Reasonable steps should be taken to respond to such a request, taking into consideration the nature of the request, the conditions of the study, and the applicable laws and regulations.

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

19. STUDY RECORD RETENTION

In compliance with the ICH GCP guidelines,[2] the Investigator/Institution will maintain all CRFs and all subject records that support the data collected from each subject, as well as all study documents as specified in ICH GCP[2] 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.

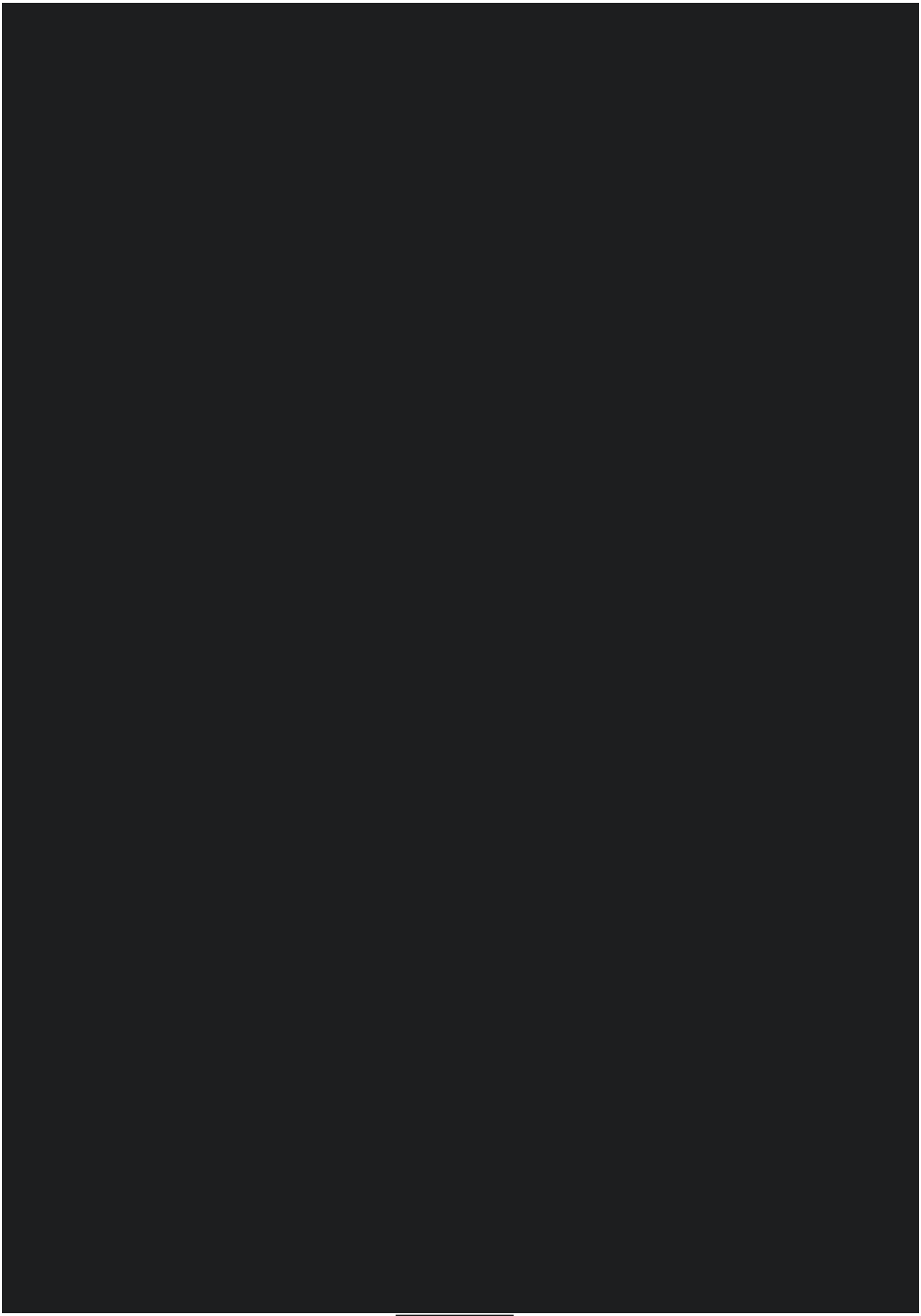
21. PUBLICATION

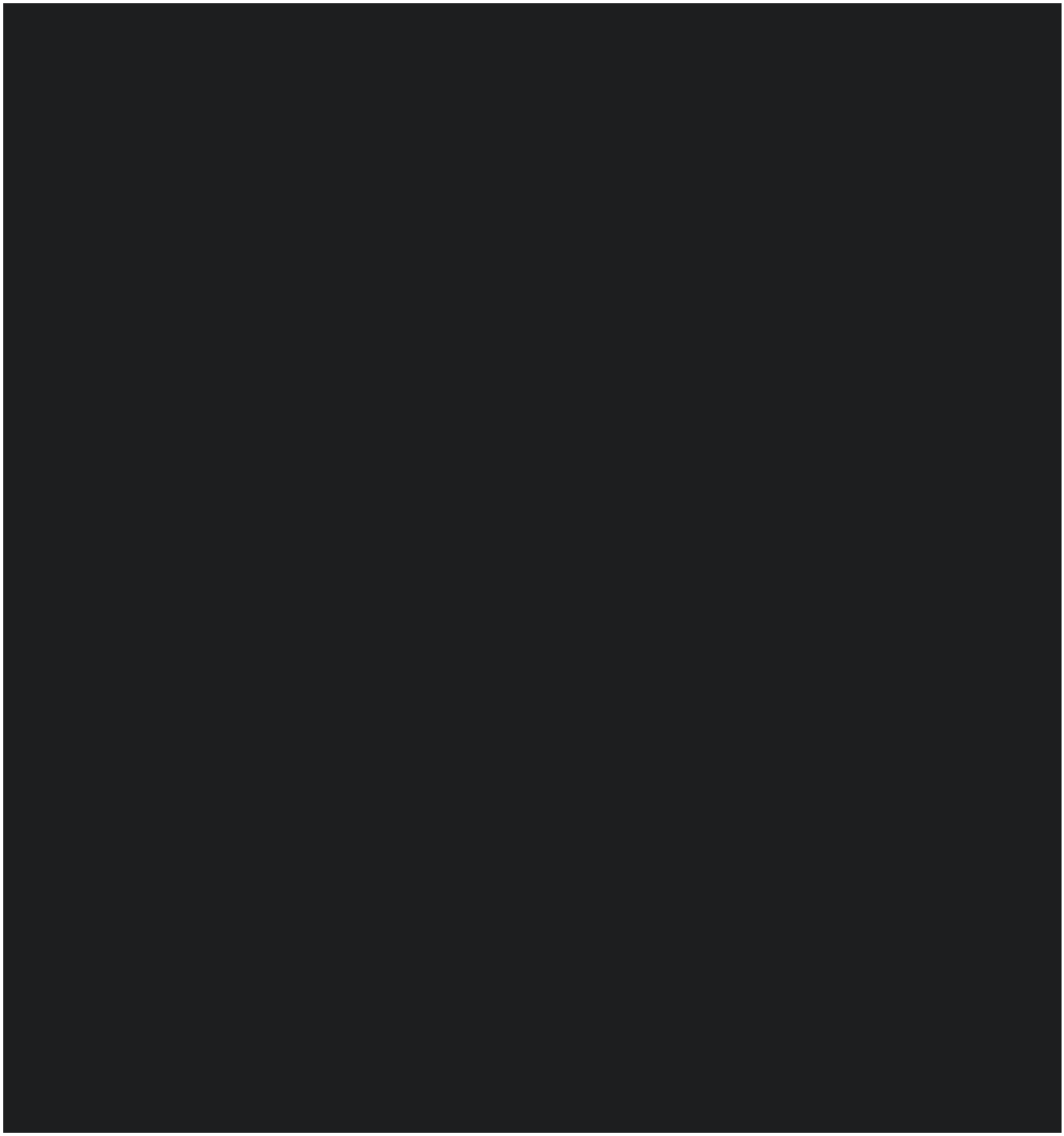
There is no plan to publish the outcome of this investigation.

22. REFERENCES

1. ISO 14155:2020: Clinical Investigation of Medical Devices for Human Subjects — Good Clinical Practice. Available at: https://www.iso.org/standard/71690.html
2. International Council for Harmonization Good Clinical Practice E6(R2) (ICH GCP). Available at: https://www.ich.org/page/efficacy-guidelines
3. Declaration of Helsinki - Ethical principles for Medical Research Involving Human Subjects. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
4. United States (US) Code of Federal Regulations (CFR). Available at: https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR
5. SAS Institute Inc. 2016 SAS/STAT® 14.3 User's Guide. Cary, NC: SAS Institute Inc.
6. Health Information Portability and Accountability Act (HIPAA). Available at: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)





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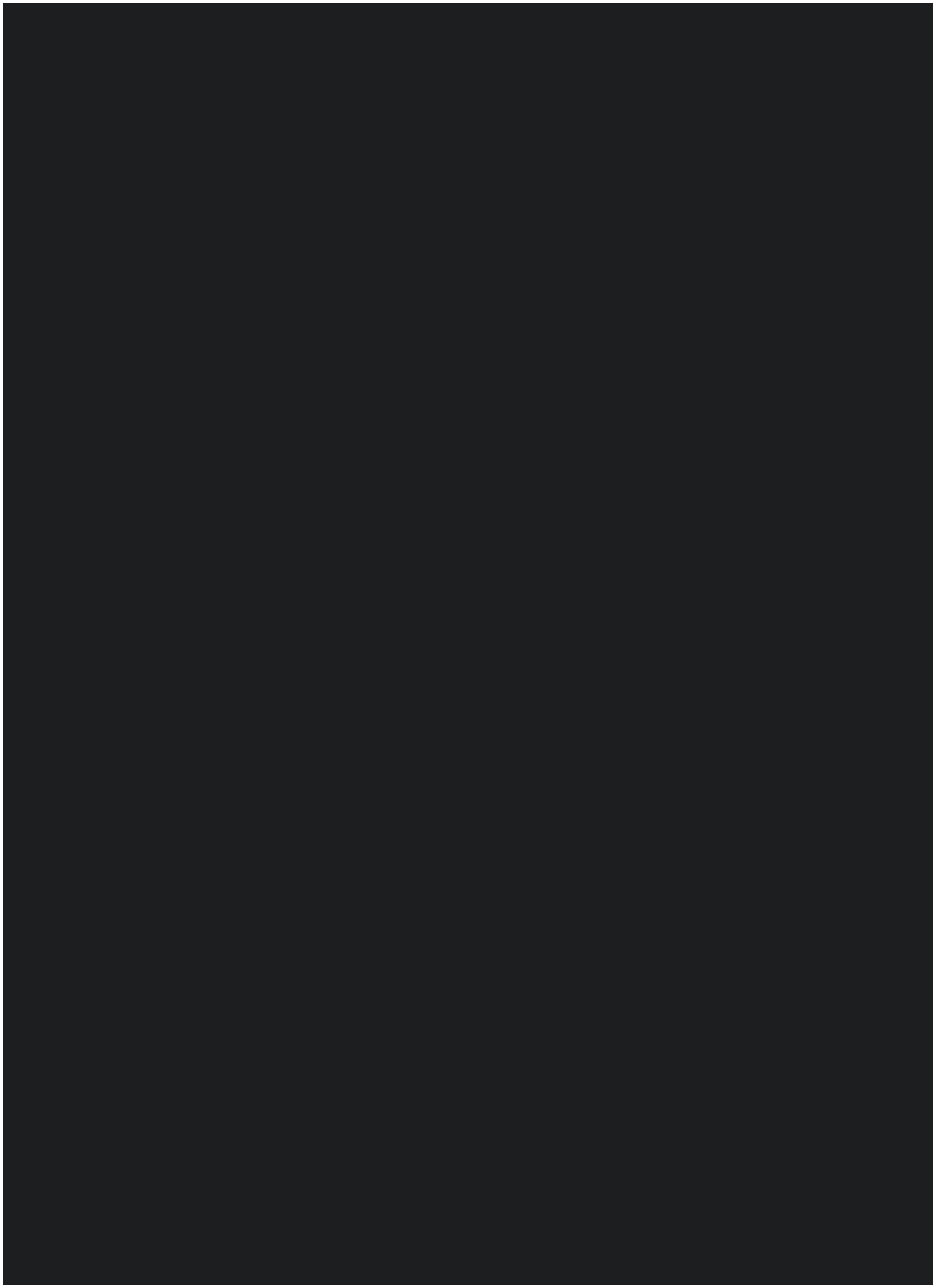

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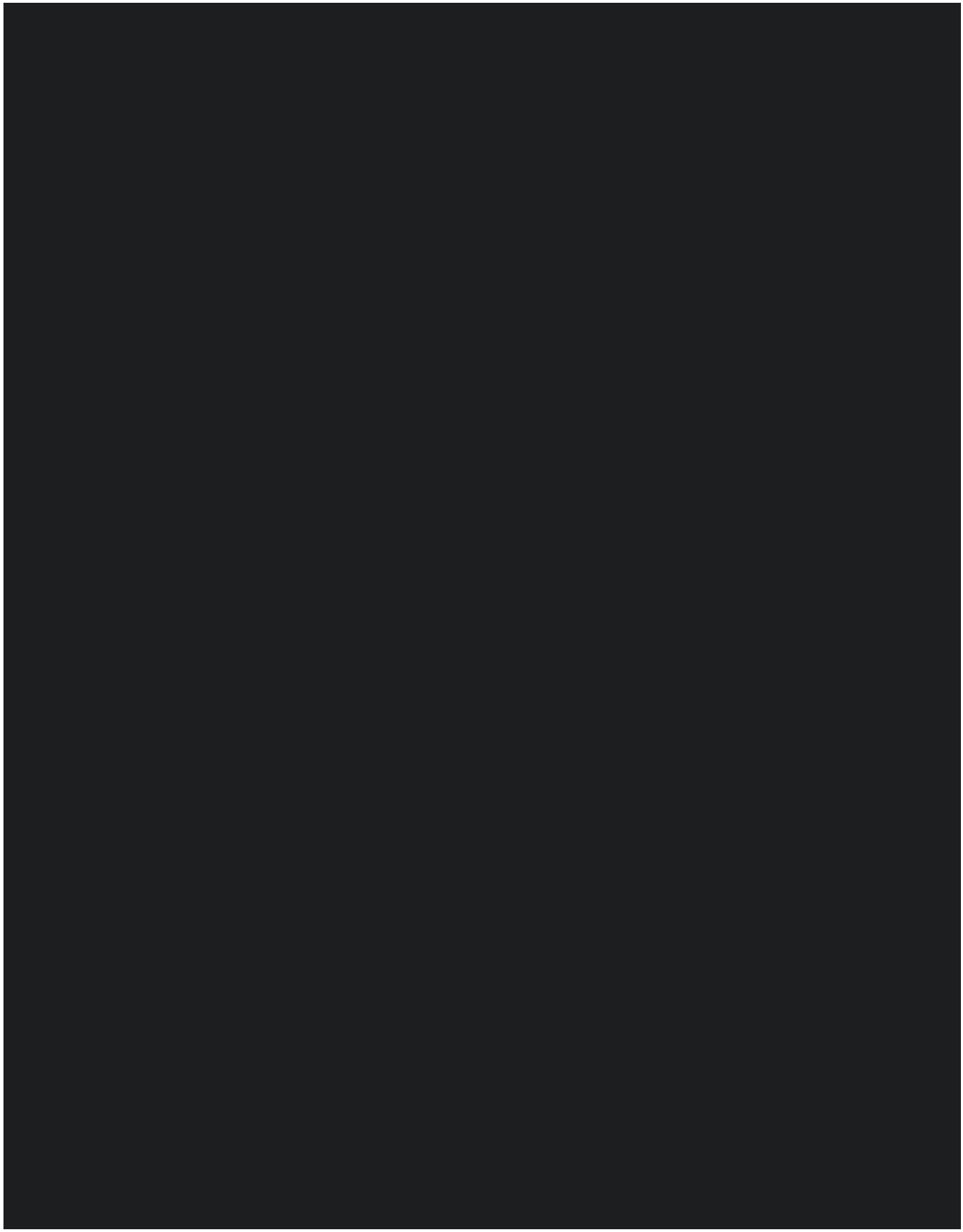
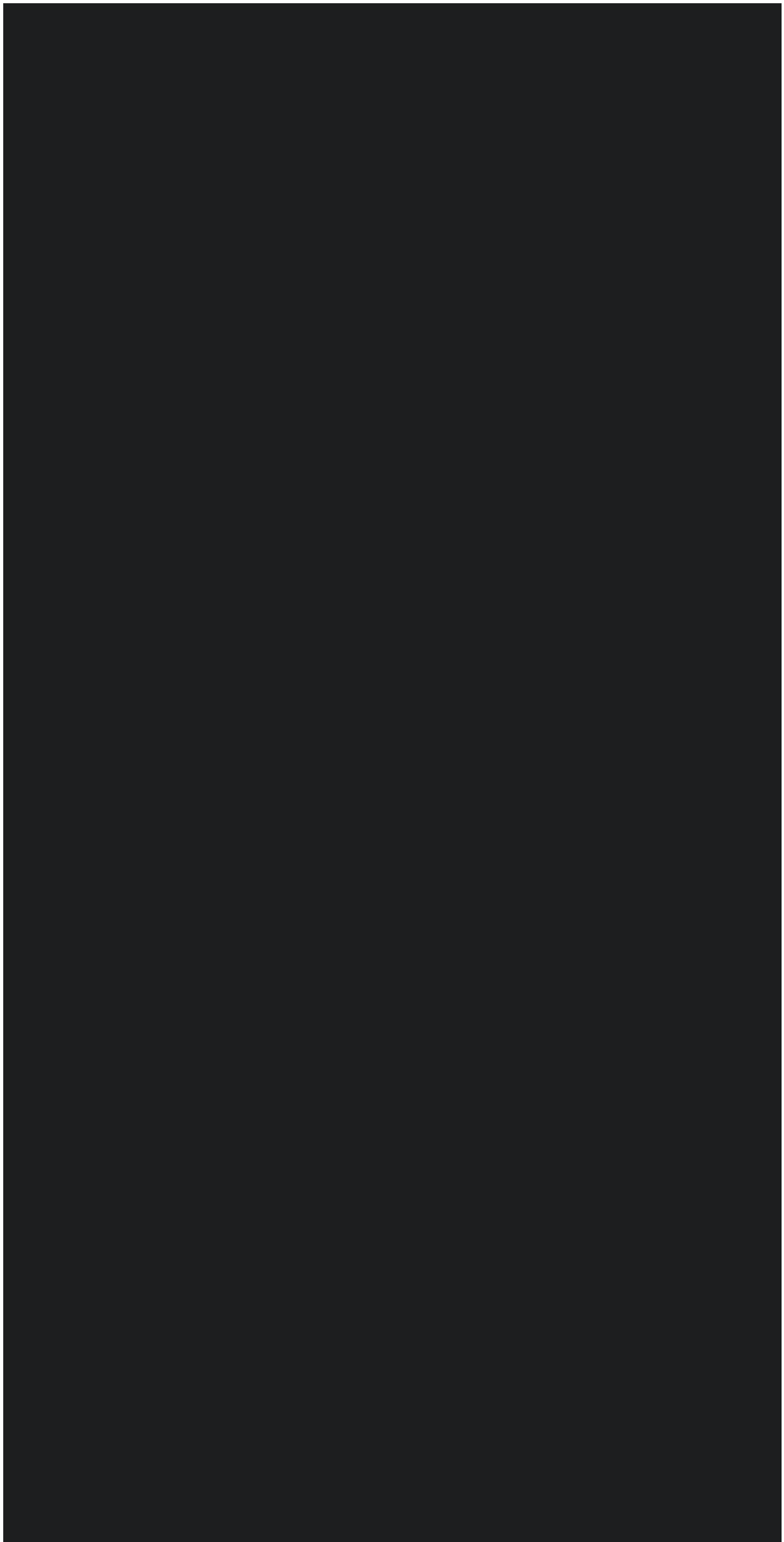




APPENDIX B: PATIENT INSTRUCTION GUIDE

A Patient Instruction Guide (PIG) will be provided separately.

APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

Alcon DAILIES TOTAL1® for Astigmatism (delefilcon A) soft contact lenses for Daily Disposable Wear.

Alcon PRECISION1® for Astigmatism (verofilcon A) soft contact lenses for Daily Disposable Wear.

Alcon	**DAILIES TOTAL1® and DAILIES TOTAL1® Multifocal** (delefilcon A) soft contact lenses for Daily Disposable Wear	W900236420

Important: This package insert is effective as of December 2019 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. Copies of this package insert are available without charge from Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com. In addition, a *Patient Instruction Booklet* is available which is recommended to be given to patients.

℞ 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® Multifocal (delefilcon A) soft contact lenses are made from a lens material that is 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, a light blue tint, which makes them easier to see when handling.

Lens Properties

- Refractive Index hydrated: 1.42
- Light Transmittance: 93% (@ 610 nm, -1.00 D)
- Oxygen Permeability (Dk): 140 x 10^{-11} (cm^2/sec)(ml O_2 /ml x mm Hg), measured at 35° C (intrinsic Dk-Coulometric method)
- Water Content: 33% by weight in normal saline
- Surface Water Content: ≥ 80%

Lens Parameters

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

Lens Parameters Available[1]

DAILIES TOTAL1® (delefilcon A) spherical contact lenses

- Chord Diameter: 14.1 mm
- Center Thickness: 0.09 mm @ -3.00 D (varies with power)
- Base Curve: 8.5 mm
- Powers: -0.50 to -6.00 D (0.25 D steps)
  -6.50 to -12.00 D (0.50 D steps)
  +0.50 to +6.00 D (0.25 D steps)

DAILIES TOTAL1® Multifocal (delefilcon A) contact lenses

- Chord Diameter: 14.1 mm
- Center Thickness: 0.09 mm @ -3.00 D (varies with power)
- Base Curve: 8.5 mm
- Powers: +6.00 D to -10.00 D (0.25 D steps)
  ADD: LO, MED, HI

NOTE: Hereafter, **DAILIES TOTAL1® spherical contact lenses** and **DAILIES TOTAL1® Multifocal contact lenses** will simply be referred to as delefilcon A contact lenses unless product distinction is necessary.

ACTIONS

When hydrated and placed on the cornea, **delefilcon A** contact lenses act as a refracting medium to focus light rays on the retina.

INDICATIONS (Uses)

DAILIES TOTAL1® (delefilcon A) spherical 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 approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES TOTAL1® Multifocal (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 (D) or less and who may have up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use, daily disposable wear. 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 contact lenses when any of the following exists:

- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease which may be exacerbated by or interferes with contact lens wear
- Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exaggerated 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
- If eyes become red or irritated

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. **Serious eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.**
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical study results have shown that the risk of serious adverse reactions is increased when contact lenses are worn overnight[2].
- Studies[2] have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- 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.

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

Due to the small number of patients enrolled in the 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, 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.

- 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.
- Patients who wear contact lenses to correct presbyopia may not achieve the best possible 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.
- Before leaving the eye care professional's office, the patient 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 instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. Alcon recommends that patients see their eye care professional once each year, or more often, as recommended by the eye care professional.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Eye Care Professionals should carefully instruct patients about the following 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 thoroughly dry hands with a lint-free towel before handling lenses.**
- **REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Always handle lenses carefully. Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use.
- 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.
- Ensure that the correct lens for each eye is available. Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand. Ensure the lens is right side out. Inspect lenses prior to insertion. Do not insert damaged lenses.
- To insert lenses:
  - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses.
  - 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 remove the hand, releasing the lower lid.
  - Look straight ahead and slowly remove the other hand, releasing the upper lid.
  - Blink gently.
- To remove lenses:
  - Wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling lenses. **Make sure hands are clean and completely dry.**
  - Blink fully several times.
  - While looking up, slide the lens down onto the white part of the eye.
  - Remove the lens by pinching gently between the 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.
- If a lens decenters on the eye, it may be possible to recenter it by:
  - Closing the eye and 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.
- If a lens tears in the eye it will feel uncomfortable. Advise wearers it is impossible to lose a contact lens or part of a contact lens behind the eye and to remain calm. Lens pieces may be removed by pinching them as for normal lens removal, carefully avoiding pinching the eye tissue. If the lens pieces do not seem to remove easily, rinsing with saline is recommended. If this does not help, the wearer should contact an eye care professional for assistance.

Lens Wearing Precautions:

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- 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 Lens* section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- The eye care professional should be consulted about wearing lenses during water sports and water related activities. Exposure to water or other non-sterile liquids while wearing

contact lenses in 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.
- 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.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of each day upon removal from the eye.
- Discard any lens which has become dehydrated or damaged. Replace with a sterile, fresh, new lens.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always carry spare lenses with you or have back-up spectacles available.
- Do not share lenses with anyone as this may spread micro-organisms which could result in serious eye health problems.
- Do not use lenses beyond their expiration date.

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 once each year or as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such 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.

Who Should Know that the Patient is Wearing Contact Lenses:
- Patients should inform their health care practitioners that they are wearing contact lenses.
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

It is strongly recommended that patients be provided with a copy of the **DAILIES TOTAL1® and DAILIES TOTAL1® Multifocal** (delefilcon A) Contact Lenses *Patient Instruction Booklet* available from Alcon and understand its contents prior to dispensing the lenses.

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
Patients should be instructed to check 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 or symptoms:
- Moderate to severe eye pain not relieved by removing the lens
- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

WHAT TO DO IF A PROBLEM OCCURS
Patients should be instructed that if any of the above signs or symptoms are noticed, he or she should:
- **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 lens(es) or upon insertion of a new lens, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
- **The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated carefully 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.

ADVERSE EFFECT REPORTING
If a patient experiences any serious adverse effects associated with the use of **DAILIES TOTAL1®** brand (delefilcon A) contact lenses, please notify: Alcon Medical Safety in the USA at 1-800-757-9780.

FITTING GUIDE AND PATIENT BOOKLET
Conventional methods of fitting contact lenses apply to delefilcon A contact lenses. For a detailed description of the fitting techniques, refer to the **DAILIES TOTAL1®** and **DAILIES TOTAL1® Multifocal** (delefilcon A) Contact Lenses *Professional Fitting and Information Guide*. Both the professional fitting guide and a patient instruction booklet are available free of charge from:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX, USA 76134-2099
1-800-241-5999

LENS WEAR & REPLACEMENT SCHEDULES
DAILY WEAR (less than 24 hours, while awake):
- To avoid tendency of the daily wear patient to over-wear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non lens wear per 24 hour period.
- It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.
- 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. There may be a tendency for patients to over-wear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that delefilcon A contact lenses are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.
- 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.

EMERGENCY LENS CARE
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.

CARE FOR A STICKING LENS
If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. It is important that the patient wash and dry their hands thoroughly before removing the lens. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

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 and rinsed and dried with a lint-free towel prior to handling a lens. In or [redacted] he blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes lenses should be disposed of after a single use and not be re-used from patient to patient.

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 or fresh saline solution and immediately contact the eye care professional or visit a hospital emergency room without delay.

DISPOSAL AND RECYCLING
Dispose of contact lenses and the blister pack lidding in the waste bin, not down the sink or toilet. 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.

HOW SUPPLIED
Each lens is packaged in a foil-sealed plastic container 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 (and ADD power for multifocal lenses), manufacturing lot number, date of manufacture, and expiration date.

The following may appear on the labels or cartons:

Symbol/Abbreviation Description

Rx only	CAUTION: Federal law (United States) restricts this device to sale by or on the order of a licensed eye care professional.
	Single sterile barrier system
STERILE	Sterilized using steam
EXP	Use-by date (Expiry date)
LOT	Batch code
en	Two letter code for the language (Example shown: English)
	Do not re-use
	Do not use if blister package is damaged
DIA	Diameter
BC	Base curve
PWR	Power
L	Left
R	Right
D	Diopter (lens power)
ADD	Addition power
MAX ADD	Maximum effective addition power
LO	Low
MED	Medium
HI	High
CE	European conformity mark
	Caution
	Consult instructions for use
EC REP	Authorized representative in the European Community
	Manufacturer
	Date of manufacture
MD	Medical device
	Packaging waste license sign

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

1-800-241-5999

www.alcon.com

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

Alcon

[1] Check for actual product availability as additional parameters may be introduced over time.
[2] 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. *N Eng J Med*. 1989; 321 (12):773-783.

IMPORTANT: This package insert is effective as of June 2020 and applicable to the verofilcon 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. Copies of this package insert are available without charge from Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com. Alcon makes available a Patient Instruction Booklet, which is recommended to be given to patients.

Rx only

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.

PRODUCT DESCRIPTION

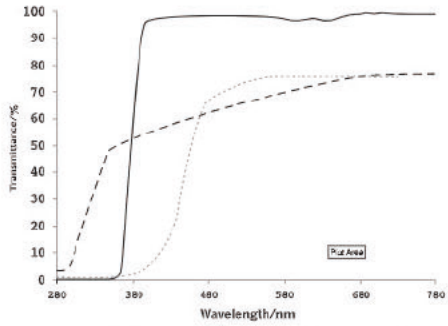
PRECISION1™ and PRECISION1™ for Astigmatism (verofilcon A) soft contact lenses are made from a lens material that is 51% water and 49% verofilcon A, a silicone containing hydrogel. The color additive Reactive Blue 247 is added to the lens material to create a light blue edge-to-edge color to make it easier to see when handling. In addition, lenses contain a benzotriazole UV-absorbing monomer 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 to 380 nm for the entire power range.

Lens Properties

Refractive Index (hydrated):	1.4
Light Transmittance:	≥ 90% (@ 640 nm, -3.00 D)
Oxygen Permeability (Dk):	90 x10 $^{-11}$ (cm^2/sec) (ml O_2 /ml x mm Hg), measured at 35 °C (intrinsic Dk-Coulometric method)
Water Content:	51% by weight in normal saline
• Diameter Range:	13.0 to 15.0 mm
• Spherical Power Range:	-20.00 to +20.00 D
• Base Curve Range:	8.0 to 9.2 mm

Transmittance Curves:

PRECISION1™ (verofilcon A) Contact Lens versus a Human Cornea and a Human Crystalline Lens



——— Verofilcon A contact lens measured through central 6 mm portion for the thinnest marketed lens (-3.00 D, 0.090 mm center thickness).

— — 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.

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

LENS PARAMETERS AVAILABLE[1]

PRECISION1™ (verofilcon A) contact lenses (spherical)

• Chord Diameter:	14.2 mm
• Center Thickness:	0.09 mm @ -3.00 D (varies with power)
• Base Curve:	8.3 mm
• Powers:	Minus: -0.50 to -6.00 D (0.25 D steps); -6.50 to -12.00 D (0.50 D steps)
	Plus: +0.50 to +6.00 D (0.25 D steps); +6.50 to +8.00 D (0.50 D steps)

PRECISION1™ for Astigmatism (verofilcon A) contact lenses (toric)

• Chord Diameter:	14.5 mm
• Center Thickness:	0.10 mm @ -3.00 D (varies with power)
• Base Curve:	8.5 mm
• Powers and Axes:	Sphere: +0.25 D to +4.00 D (0.25 D steps) Cylinder: -0.75 D, -1.25 D, -1.75 D Axes: 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°
	Cylinder: -2.25 D Axes: 10°, 20°, 160°, 170°, 180°
	Sphere: Plano (0.00 D) to -6.00 D (0.25 D steps) Cylinder: -0.75 D, -1.25 D, -1.75 D Axes: 10° to 180° (full circle, in 10° steps)
	Cylinder: -2.25 D Axes: 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°
	Sphere: -6.50 D to -8.00 D (0.50 D steps) Cylinder: -0.75 D, -1.25 D, -1.75 D Axes: 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180°
	Cylinder: -2.25 D Axes: 10°, 20°, 160°, 170°, 180°

ACTIONS

When hydrated and placed on the cornea, **verofilcon A** contact lenses act as a refracting medium to focus light rays on the retina.
The lenses contain a UV blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye. The thinnest **verofilcon A** lenses (-3.00 diopters) block 93% UVA radiation and 99% UVB radiation. The degree of UV radiation blockage will increase for thicker lenses. Patients should be advised of the following: 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-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders.

INDICATIONS (Uses)

PRECISION1™ (verofilcon A) spherical 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 approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

PRECISION1™ for Astigmatism (verofilcon A) toric 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 6.00 diopters (D) or less of astigmatism.

The lenses are to be prescribed for single use, daily disposable wear. 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 verofilcon A contact lenses when any of the following exists:

- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease which may be exacerbated by or interferes with contact lens wear
- Allergic reactions or irritation of the ocular surfaces or adnexa that may be caused by or exaggerated 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
- If eyes become red or irritated

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.**
- 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 serious adverse reactions is increased when lenses are worn overnight.
- Studies[2] have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- 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.

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:

Due to the small number of patients enrolled in the 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, 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.

- 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.
- Before leaving the eye care professional's office, the patient 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 instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. Alcon recommends that patients see their eye care professional once each year, or more often, as recommended by the eye care professional.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Eye Care Professionals should carefully instruct patients about the following 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 thoroughly dry hands with a clean lint-free towel before handling lenses.**
- **REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Always handle lenses carefully. Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use.
- Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand. Ensure the lens is right side out and that the correct lens for each eye is available. Inspect lenses prior to insertion. Do not insert damaged lenses.
  - To insert lenses:
    - 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 remove the hand, releasing the lower lid.
    - Look straight ahead and slowly remove the other hand, releasing the upper lid.
    - Blink gently.
  - To remove lenses:
    - **Make sure hands are clean and completely dry.**
    - Blink fully several times.
    - While looking up, slide the lens down onto the white part of the eye.
    - Remove the lens by pinching gently between the 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.
- If a lens decenters on the eye, close the eye and gently massage the eyelid to return the lens to the central position. If the problem persists, consult the eye care professional.
- If a lens tears in the eye it will feel uncomfortable. Advise wearers it is impossible to lose a contact lens or part of a contact lens behind the eye and to remain calm. Lens pieces may be removed by pinching them as for normal lens removal, carefully avoiding pinching the eye tissue. If the lens pieces do not seem to remove easily, rinsing with saline is recommended. If this does not help, the wearer should contact an eye care professional for assistance.

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.

Lens Wearing Precautions:

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- 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 Lens* section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- The eye care professional should be consulted about wearing lenses during water sports and water related activities. Exposure to water or other non-sterile liquids while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to *Acanthamoeba* keratitis.
- 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.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Lenses should be disposed of each day upon removal from the eye.
  - Discard any lens which has become dehydrated or damaged. Replace with a sterile, fresh, new lens.
  - Note the correct lens power for each eye to prevent getting them mixed up.
  - Always keep a supply of replacement lenses on hand.
  - Do not use lenses beyond their expiration date.

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 once each year or as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such 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.

Who Should Know that the Patient is Wearing Contact Lenses:

- Patients should inform their health care professionals that they are wearing contact lenses.
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

[1]Check for actual product availability as additional parameters may be introduced over time.

[2]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. *New England Journal of Medicine*, Septem[redacted]

It is strongly recommended that patients be provided with a copy of the *Patient Instruction Booklet* available from Alcon and understand its contents prior to dispensing the lenses.

ADVERSE EFFECTS

Patients should be instructed to check 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 or symptoms:

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

Patients should be instructed that if any of the above signs or symptoms is noticed, he or she should:

- **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 lens(es) or upon insertion of a new lens, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
- **The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated carefully 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.

ADVERSE EFFECT REPORTING

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

FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to **verofilcon A** contact lenses. For a detailed description of the fitting techniques, refer to the **PRECISION1™ (verofilcon A)** contact lenses *Professional Fitting and Information Guide*. Both the professional fitting 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 & REPLACEMENT SCHEDULES

Daily Wear (less than 24 hours, while awake):

- It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.
- 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. There may be a tendency for patients to over wear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that **verofilcon A** contact lenses are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24-hour period. Optimum individual wearing schedules will vary.

Verofilcon 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.

EMERGENCY LENS CARE

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.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. It is important that the patient wash and dry their hands thoroughly before removing the lens. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

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 and 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 lenses should be disposed of after a single use and not be re-used from patient to patient.

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 or fresh saline solution and immediately contact the eye care professional or visit a hospital emergency room without delay.

DISPOSAL AND RECYCLING

Dispose of contact lenses and the blister pack lidding in the waste bin, not down the sink or toilet. 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.

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic 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, manufacturing lot number, date of manufacture (when available), and expiration date.

Lenses are supplied sterile in cartons containing up to 90 individually sealed contact lenses.

The following may appear on labels or cartons:

SYMBOL / ABBREVIATION	DESCRIPTION
Rx only	CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.
	Single sterile barrier system
STERILE	Sterilized using steam
EXP	Use-by date (Expiry date)
LOT	Batch code
en	Two letter code for the language (Example shown: English)
	Do not re-use
MD	Medical device
	Do not use if blister package is damaged
CE	European conformity mark
	Authorized representative in the European Community
	Packaging waste license sign
	Caution
	Consult instructions for use
	Manufacturer
	Date of manufacture
PWR	Power
D	Diopter (lens power)
DIA	Diameter
BC	Base curve
L	Left
R	Right
UV	Ultra-violet
UVA	Ultra-violet A
UVB	Ultra-violet B
CYL	Cylinder power

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

www.alcon.com

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

Date: June 2020

Alcon

APPENDIX D: [redacted]

- [redacted] LENS FITTING CHARACTERISTICS
- [redacted] SUBJECT REPORTED OCULAR SYMPTOMS
- [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS
- [redacted] BIOMICROSCOPY SCALE
- [redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION
- [redacted] TORIC FIT EVALUATION
- [redacted] ETDRS DISTANCE VISUAL ACUITY MEASURMENT PROCEDURE
- [redacted] PATIENT REPORTED OUTCOMES
- [redacted] LENS INSERTION AND REMOVAL
- [redacted] VISUAL ACUITY CHART LUMINANCE AND ROOM ILLUMINATION TESTING

[redacted] LENS FITTING CHARACTERISTICS

[redacted]

[redacted]

[redacted]

[redacted]

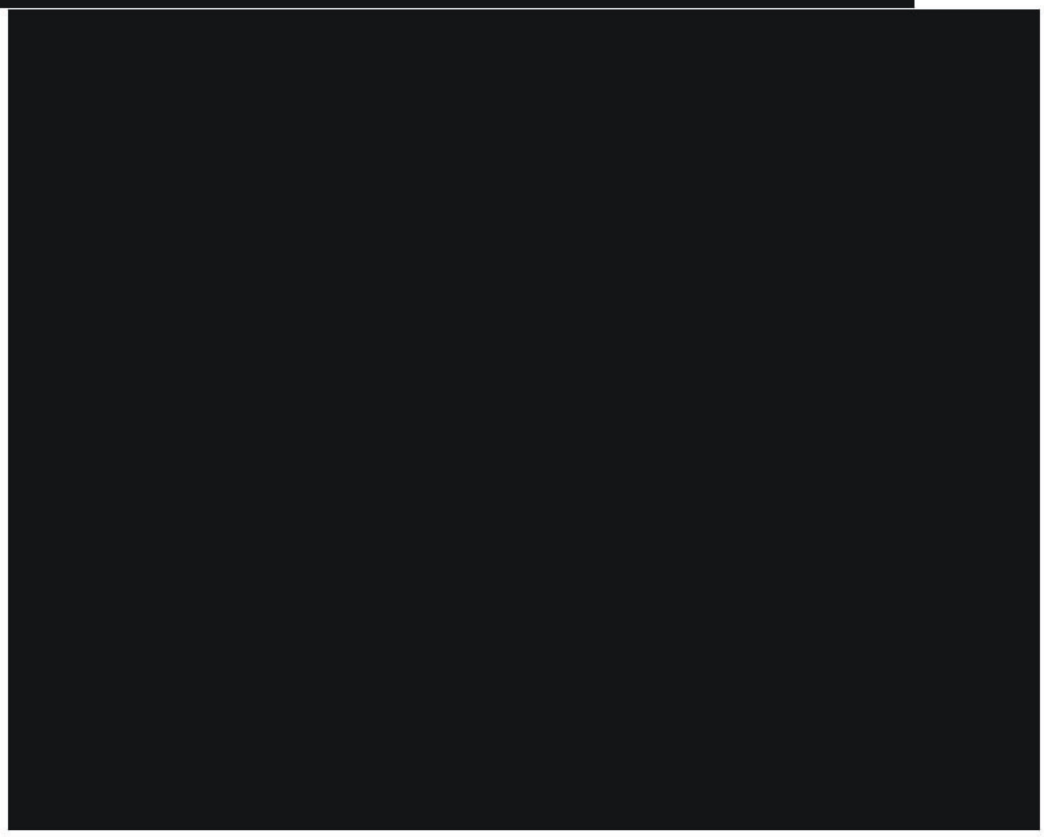
[redacted]

[redacted] SUBJECT REPORTED OCULAR SYMPTOMS

[redacted]

[redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS

[redacted]



[redacted]

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[redacted] **BIOMICROSCOPY SCALE**

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[redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] TORIC FIT EVALUATION

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] DISTANCE LOGMAR VISUAL ACUITY MEASUREMENT PROCEDURE

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] PATIENT REPORTED OUTCOMES

[redacted]

[redacted] LENS INSERTION AND REMOVAL

[redacted]

[redacted]

[redacted]

[redacted] VISUAL ACUITY CHART LUMINANCE AND ROOM ILLUMINATION TESTING

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

APPENDIX E: [redacted] GUIDELINES FOR COVID-19 RISK MITIGATION

1.0 PURPOSE

The purpose of this document is to provide guidelines for the re-opening or initiation of clinical study sites participating in Johnson & Johnson Vision Care, Inc. (JJVCI) clinical studies during the COVID-19 pandemic.

2.0 SCOPE

This document provides guidelines for Johnson & Johnson Vision Care (JJVCI) to address the potential risks from COVID-19 to study subjects, investigators, study site staff, and monitors at study sites. The guidance provided in this document is in effect from the date of approval through the date of retirement of this Work Instruction. At a minimum, this Work Instruction will be reviewed and updated on a quarterly basis, as appropriate.

NOTE: Re-opening of sites outside of the US will be evaluated on a country by country basis subject to local health authority guidance.

3.0 DEFINITIONS

American Academy of Optometry (AAO): The American Academy of Optometry is an organization of optometrists based in Orlando, Florida. Its goal is to maintain and enhance excellence in optometric practice, by both promoting research and the dissemination of knowledge. The AAO holds an annual meeting, publishes a monthly scientific journal, gives credentials to optometrists through the fellowship process and publishes position statements.

American Optometric Association (AOA): The American Optometric Association, founded in 1898, is the leading authority on quality care and an advocate for our nation's health, representing more than 44,000 Doctors of Optometry (O.D.), optometric professionals, and optometry students. Doctor of Optometry take a leading role in patient care with respect to eye and vision care, as well as general health and well-being. As primary health care providers, Doctor of Optometry have extensive, ongoing training to examine, diagnose, treat and manage ocular disorders, diseases and injuries and systemic diseases that manifest in the eye. The American Optometric Association is a federation of state, student, and armed forces optometric associations. Through these affiliations, the AOA serves members consisting of optometrists, students of optometry, paraoptometric assistants and technicians. The AOA and its affiliates work to provide the public with quality vision and eye care.

Centers for Disease Control and Prevention (CDC): The Centers for Disease Control and Prevention is a national public health institute in the United States. It is a United States federal agency, under the Department of Health and Human Services, and is headquartered in Atlanta, Georgia.

COVID-19: Current outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19).

Clinical Study: Voluntary research studies conducted in people and designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments. May also be called clinical trials, studies, research, trials, or protocols.

Clinical Study Site: Location where a clinical study is conducted, such as a doctor's office, university, or laboratory. Clinical studies are conducted by Investigators who are individual(s) responsible for the conduct of the clinical study at a study site. If a study is conducted by a team of individuals, the Investigator is the responsible leader of the team and may be called the Principal Investigator.

Clinical Operations Manager (COM): The Johnson & Johnson Vision Care (JJVCI) individual responsible for the overall management of a clinical trial.

Monitor: An individual designated to oversee the progress of a clinical study and ensure that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and applicable regulatory requirements.

Medical Safety Officer (MSO): Physician who has primary accountability in their product portfolio for product health and safety, and who serves as an independent medical voice for patient safety.

Safety Management Team (SMT): A cross-functional, collaborative team responsible for review, assessment and evaluation of medical safety data arising from any source throughout the product life cycle.

4.0 GUIDANCE FOR STUDY DOCUMENTS

In alignment with recent health authority guidance, JJVCI is providing recommendations for study-related management in the event of disruption to the conduct of the clinical study. This guidance does not supersede any local or government requirements or the clinical judgement of the investigator to protect the health, safety and well-being of participants and site staff. If, at any time, a participant's safety is considered to be at risk, study intervention will be discontinued, and study follow-up will be conducted as outlined in the protocol.

During the COVID-19 pandemic, the additional risks listed below need to be considered for study participants and study personnel:

4.1 Additional Risks Related to the COVID-19 Pandemic:

- The possible transmission of the Coronavirus infection and consequent complications, beyond the risk of adverse events due to the investigational device and/or procedures.
- The risk may be higher in an optometric clinical study because of the close contact the subject will have with health care professionals during the procedures and assessments (since the investigator must make the measurements close to the subject's face) and, in addition the need for multiple follow-up visits/exams which may expose the subject to other patients and/or healthcare professionals who might be transmitting the virus, even if they do not have symptoms.
- Potential disruptions to the study may be necessary due to current or future pandemic-related emergency restrictions, which may lead to delays in scheduled follow-up visits.
- Subjects experiencing an adverse event related to contact lens wear may receive delayed treatment due to COVID-19 restrictions. In this event, all assessments that can be conducted virtually will be completed by the investigator to determine the best course of treatment for the subject, including an unscheduled visit, up to discontinuation from the study, as appropriate.

If a study subject is found to have contracted COVID-19 during participation in a study, he/she will be discontinued from the study and followed until COVID-19 Adverse Event (AE) resolution.

To help minimize the above potential risks, JJVCI recommend reviewing/complying with local, state, and governmental guidance for COVID-19 risks.

JJVCI will provide the following study specific documents with language pertaining to COVID-19 risks:

4.1.1 Informed Consent:

Will include information concerning the study-associated risks related to the COVID-19 pandemic in bold font and/or boxed on the first page of the Informed Consent document:

STUDY ASSOCIATED RISKS RELATED TO COVID-19 (CORONAVIRUS) PANDEMIC

It is important to note that this study will be conducted, at least in part, during the COVID-19 pandemic. As such, additional risks associated with the infection with COVID-19 exist for you. This is particularly important for this study due, in part, to the closeness of the doctor during the study examinations.

The potential effects of the disease are not fully known, at this time, and may include long-term serious health consequences. In severe cases, this may result in hospitalization and/or death. Based on current knowledge from the Centers for Disease Control and Prevention (CDC), those at high-risk for severe illness from COVID-19 include older adults and people with underlying medical conditions.

During this study, all appropriate measures will be taken to minimize risks including the use of personal protective equipment such as masks and gloves, as well as proper sanitization. This is in conformance to guidance from the CDC, local health departments, and the state and county in which the study doctor's office is located. However, these measures may not completely eliminate the risks associated with contracting COVID-19.

If you are found to have contracted COVID-19 or feel ill with flu-like symptoms during participation in the study, you will not be permitted to continue in-office study follow-up visits, but you will receive instructions and your condition will be monitored by the doctor and/or study staff.

4.1.2 COVID-19 Risk Control Checklist (Attachment-B):

Will include COVID-19 risk control methods that are required by a site to conduct JJVCI clinical studies. The risk controls are consistent with CDC, AOA, AAO Guidance. The Principal Investigator will review/sign the study specific checklist prior to the Site Initiation Meeting.

4.1.3 Protocol Compliance Investigator(s) Signature Page:

Will include a statement indicating that the Principal Investigator (PI) agrees to conduct the study in compliance with all local, state, and governmental guidance's for COVID-19 risk mitigation.

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

4.1.4 Study Site Initiation Training Slides:

Will include suggestions to help mitigate potential transmission of COVID-19. Suggestions may include maintaining social distancing in the clinical site by staggered scheduling of study patients, wearing proper PPEs, frequent disinfection, and installing shields on the slit lamp and other applicable equipment.

5.0 GUIDANCE FOR REMOTE SUBJECT VISITS

Potential disruptions to the study may be necessary due to current or future pandemic-related emergency restrictions. Possible disruption of the study as a result of COVID-19 control measures may lead to delays in scheduled follow-up visits.

Subjects may be delayed in being seen for study follow up visit(s), for example due to COVID-19 control measures or due to the subject's concerns or fears about COVID-19 risk. When appropriate, the remote assessment will be conducted to the extent possible. Discussions with the subject during remote assessments may include:

Procedure	Details
Subject Reported Ocular Symptoms	Subjects will respond to a verbal open-ended symptoms questionnaire regarding the test article when applicable and feasible.
Change of Medical History (Adverse Events) and Concomitant Medications / Therapies Review	Record any adverse events or medical history changes from the previous study visit with the subject/parents. Review the subject's concomitant medications/therapies and record any changes from the previous study visit.
Wearing Time and Compliance	Record the average wearing time (including number of hours per day during weekdays and weekends, and number of days per week). Confirm compliance with the prescribed wear schedule. • Record and discuss the lens wear compliance based on the subject's self-report. For example, the subjects will be asked the time of the day the subject typically puts on the study lenses in the morning and takes off in the evening, the number of days per week lenses were worn, and the number of consecutive days the subject didn't wear the study lenses, etc.

The discussion with the subject will be documented in EDC under Tele-Visit and a minor protocol deviation will be noted. If during the telephone consultation, a subject states he/she wishes to discontinue participating in the study, instruct the subject to stop wearing the study lenses and schedule the subject to return to the clinic for a Final Evaluation at the at earliest possible time. Subjects should return all unused lenses to the clinic at the last visit.

Changes in study visit schedules, missed visits, or participant discontinuations may lead to missing data, including data related to protocol-specified procedures. Case report forms should capture specific information regarding the basis of missing data, including the relationship to the COVID-19 pandemic.

6.0 STUDY CONDUCT DURING PANDEMIC

It is recognized that the Coronavirus Disease 2019 (COVID-19) pandemic may have an impact on the conduct of this clinical study due to, for example, self-isolation/quarantine by participants and study-site personnel; travel restrictions/limited access to public places, including Optometry Clinics; and changes in clinic procedures required to address the COVID-19 challenge.

Every effort should be made to adhere to protocol-specified assessments for study participants, including follow-up. However, if scheduled visits cannot be conducted in person at the study site it is suggested that assessments be performed to the extent possible remotely/virtually or delayed until such time that on-site visits can be resumed in order to continue participant monitoring in accordance with the protocol where possible. At each contact, participants will be interviewed to collect safety data. Key efficacy endpoint assessments should be performed if required and as feasible.

Modifications to protocol-required assessments may be permitted via COVID-19 Appendix after consultation with the participant, investigator, and the sponsor. Missed assessments/visits will be captured in the clinical trial management system for protocol deviations. Interruptions of test article wear or discontinuations of study interventions and withdrawal from the study should be documented with the prefix "COVID-19-related" in the case report form (CRF).

The sponsor will continue to monitor the conduct and progress of the clinical study, and any changes will be communicated to the sites and to the health authorities according to local guidance.

If a participant has tested positive for COVID-19, the investigator should contact the sponsor's responsible medical monitor to discuss initial plans for study intervention and follow-up. The medical monitor will notify the Safety Management Team of any subject(s) that have reported "COVID-19", "Asymptomatic COVID-19", or "Suspected COVID-19" adverse events within 24 hours of the notification.

Modifications made to the study conduct as a result of the COVID-19 pandemic will be summarized in the clinical study report.

COVID-19 screening procedures that may be mandated by local healthcare systems do not need to be reported as an amendment to the protocol even if done during clinical study visits.

6.1 Monitoring Visits

When on-site monitoring by the sponsor is not feasible, the sponsor's site monitor will contact the study site to schedule remote visits. In such cases, on-site monitoring visits will resume when feasible, with increased frequency to address the source data verification backlog.

Even with staffing limitations during this COVID-19 pandemic, all routine operations related to clinical trials should be well-documented and archived as part of standard process. When conditions permit, all parties involved in this clinical trial should communicate relevant information in a timely manner so that all relevant parties remain sufficiently informed.

6.1.1 Study Site Initiation:

During the period that this Work Instruction is in effect, Site Initiation Meetings and training of study site staff will be conducted remotely. The JJVCI study team will conduct training via Skype, Zoom, Microsoft Teams or similar software as well as utilize online training materials, as applicable. Study site training will be documented utilizing Site Initiation Report [redacted] per Study Site Initiation [redacted]

On-site visits may be considered when, for example, hands-on training or evaluation of site facilities is required. While on site, the Clinical Research Associate (CRA) will follow all local, state, and governmental policies for COVID-19 Risk Mitigation, including social distancing, wearing of PPE, etc. as applicable for the location of the study site.

6.1.2 Interim Monitoring Visits (if applicable):

During the period that this Work Instruction is in effect, Interim Monitoring On-site visits will be kept to a minimum and include only those tasks that the CRA cannot perform remotely (e.g., source document verification, test article reconciliation, etc.).

To ensure data integrity during the conduct of all JJVC studies, clinical study teams will follow the study specific Clinical Monitoring Plan [redacted]

While on site, the CRA will follow all local, state, and governmental policies for COVID-19 Risk Mitigation, including social distancing, wearing of PPE, etc. as applicable for the location of the study site.

6.1.3 Study Site Closure:

During the period that this Work Instruction is in effect, the duration of the Study Site Closure Visit will be limited to tasks that the CRA cannot perform remotely (e.g., source document verification, test article final reconciliation and return, etc.).

Attachment A: Study Site Correspondence

XXXX XX, 2020

Re: COVID-19 Mitigation Plan, <<CR-xxxx/protocol title>>

Dear <<Principal Investigator>> and Study Team,

Coronavirus (COVID-19) has impacted several communities and business activities over the past several months. While we work toward the successful conduct of clinical studies, our commitment continues to be the safety of patients, healthcare professionals, and to our communities.

Therefore, we would like to share the following revisions/additions related to the above referenced Johnson & Johnson Vision Care company sponsored clinical trial(s) you are currently working on or considering participation within.

Protocol:

- Guidelines for COVID-19 Risk Mitigation provided in the Appendix section.

Protocol Signature Page:

- Will include a statement indicating the Principal Investigator agrees to conduct the study in compliance with all local, state, and governmental guidelines for COVID-19 risk mitigation.

Informed Consent:

- Will include information concerning the study-associated risks related to the COVID-19 pandemic in bold font and/or boxed on the first page of the Informed consent document.

COVID-19 Risk Control Checklist for Clinical Studies:

- Will include COVID-19 risk control measures that are required to ensure the safety and health of subjects, site staff and monitors during the pandemic.

We want to encourage the need for open lines of communication about potential challenges you may foresee as the result of the current COVID-19 situation. Therefore, we encourage you to regularly connect with your respective Johnson & Johnson clinical study team (Clinical Research Associate (CRA), Lead CRA or Study Managers).

Thank you for your continued engagement, collaboration, and dedication to your study subjects during this challenging time.

Please file this letter in your site file study correspondence.

COVID-19 Risk Control Checklist (Attachment-B):

Study Number
Site Number
Principal Investigator (PI) Name

The following COVID-19 risk control methods are required to conduct Johnson & Johnson Vison Care clinical studies. Please review the following requirements and Initial each requirement.

PI Initials	General Site Safety Planning Measures
	Signage within site describing Risk Control methods
	Social Distancing practices throughout site (waiting rooms, lobby, exam rooms, etc.)
	Non-contact thermometer available to assess temperatures of staff and patients
	Training on patient flow and physical distancing in waiting room
	Establish longer time frame between patient appointments to reduce persons in the site
	Staff should receive job-specific training on PPE and demonstrate competency with selection and proper use of PPE and wear at all times during interactions with subjects (e.g., putting on and removing without self-contamination)

PI Initials	Site Staff Daily Safety Measures
	As part of routine practice, site staff should regularly monitor themselves for fever and symptoms of COVID-19, including temperature checks
	Any staff member (including non-study clinic staff and Investigators) showing signs of being sick or testing positive for COVID-19 must not be permitted to work on activity that may expose study related staff and subject and the Sponsor shall be informed **NOTE: Inform JJVC in 24 hours of any COVID-19 cases and all potential exposure during the clinical study.**
	Ensure that all staff wear a mask Gloves should be required when working directly with patients and changed between each patient
	Have staff thoroughly wash hands for at least 20 seconds or use an alcohol-based hand sanitizer when they arrive, before and after each patient, before eating and after using the bathroom.
	Cleaning and disinfection procedures for exam rooms and instruments or equipment between patients with gloves.
	Cleaning and disinfection procedures for commonly touched surfaces (doors, chairs, computers, phones, etc.) with gloves.

PI Initials	Before a Patient or Study Visit:
	Patients should be asked prior to entering the site about fever and respiratory illness and whether they or a family member have had contact with another person with confirmed COVID-19 in the past 14 days. Patients exhibiting signs of being sick should be rescheduled when their symptoms resolve.
	Instruct patients that companions should remain outside of the facility and not accompany the patient into the facility unless they are a parent/guardian of the patient or if they are a true caregiver and need to assist the patient
	Request the patient to call or text the office upon arrival so entrance to and movement through facility can be coordinated by site staff

PI Initials	Patients Entering the site:
	Temperature checks utilizing a non-contact thermometer for all patients and companions entering the site.
	All patients and companions must wear cloth or disposable mask at all times in the site
	Maintain social distancing. Waiting rooms or lobbies should be as empty as possible. Advise seated patients to remain at least 6 feet from one another.
	Communal objects in (e.g. toys, reading materials, etc.) should be removed or cleaned regularly.

I certify that I have read and agree to implement all the listed COVID-19 Risk Control Measures required for the conduct of Johnson & Johnson Vision Care studies.

Principal Investigator Signature and Date

RESOURCE LINKS

US Resource Links

- OSHA Training
  https://www.osha.gov/SLTC/covid-19/controlprevention.html

  Personal Protective Equipment (PPE) Training
  CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html

- I&R Training
  ACUVUE® LensAssist: https://www.acuvue.com/lensassist

- Clinic Preparedness Guides
  CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinic-preparedness.html
  AOA: https://aoa.uberflip.com/i/1240437-aoa-guidance-for-re-opening-practices-covid·19/1?m4=
  American Optometric Association: https://www.aoa.org/optometry-practice-reactivation-preparedness-guide

- ln-Office Disinfection of Multi-Patient Use Diagnostic Contact Lenses
  https://www.gpli.info/wp-content/uploads/2020/03/2020-01-15-in-office-disinfecting-of-diagnostic-lenses.pdf

OUS Resource Links

- Updates on local regulations in Hong Kong
  https://www.coronavirus.gov hk/eng/index.html

- Resumption of optical services in England: Letter from Matt Neligan and Poonam Sharma
  https://www.england nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/04/C0601-reopening-of-optical-services-letter-17-june-2020.pdf

- NHS Optical Letter
  https://www.england nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/04/C0127-optical-letter-1-april-2020.pdf

- The College of Optometrists primary eye care COVID-19 guidance: Red phase
  https://www.college-optometrists.org/the-college/media-hub/news-listing/coronavirus-covid-19-guidance-for-optometrists.html

- The College of Optometrists COVID-19: College updates
  https://www.college-optometrists.org/the-college/media-hub/news-listing/coronavirus-2019-advice-for-optometrists html#CollegeGuidelines

- Infection Control Guidelines. (n.d.). Retrieved from Canadian Association Of Optometrists: https://opto.ca/sites/default/files/resources/documents/infection_control_guidelines_2016.pdf

- Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings. (2020, May 23 May). Retrieved from Government of Canada: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/interim-guidance-outpatient-ambulatory-care-settings html

- Information for Members On Coronavirus (COVID-19). (n.d.). Retrieved from Canadian Association Of Optometrists: https://opto.ca/sites/default/files/resources/documents/information_for_members_on_coronavirus.pdf

- Coronavirus (COVID-19) resources for health professionals, including aged care providers, pathology providers and health care managers. (2020, September 24). Retrieved from Australian Government Department of Health: https://www health.gov.au/resources/collections/coronavirus-covid-19-resources-for-health-professionals-including-aged-care-providers-pathology-providers-and-health-care-managers

- Environmental Cleaning and Disinfection Principles for COVID-19. (n.d.). Retrieved from Australian Government Department of Health: https://www.health.gov.au/sites/default/files/documents/2020/03/environmental-cleaning-and-disinfection-principles-for-covid-19.pdf

- Infection control guidelines and advice. (n.d.). Retrieved from Optometry Australia : https://www.optometry.org.au/practice-professional-support/coronavirus-covid-19-what-optometrists-need-to-know/covid-19-clinical-advice/infection-control-guidelines-and-advice/

PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR-6493 Clinical Evaluation of Delefilcon A and Verofilcon A Daily Disposable Toric Soft Contact Lenses Over One Week of Wear

Version and Date: 1.0 22 July 2022

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] GCP and ICH guidelines,[2] the Declaration of Helsinki,[3] United States (US) Code of Federal Regulations (CFR),[4] and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. The Principal Investigator is responsible for ensuring that all clinical site personnel, including Sub-Investigators adhere to all ICH[2] regulations and GCP guidelines regarding clinical trials during and after study completion.

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

I am responsible for ensuring that all clinical site personnel including Sub-Investigators adhere to all ICH[2] regulations and GCP guidelines regarding clinical trials during and after study completion.

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

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

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

I have read the suggested guidance provided by JJVCI pertaining to the COVID-19 risk mitigation, (COVID-19 Work Instruction in the Appendix E 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