BAUSCH + LOMB

A Study to Evaluate the Product Performance of a New Silicone Hydrogel Contact Lens

PROTOCOL

STUDY #893

Sponsor:

Bausch + Lomb Incorporated

This clinical investigation is being conducted in accordance with 21 Code of Federal Regulations (CFR) Parts 11, 50, 54, 56, and 812. The protocol was developed with consideration of the provisions in: International Organization for Standardization (ISO) 14155-1:2011 Clinical investigation of medical devices for human subjects – Part 1: General requirements; 14155-2:2011 Part 2: Clinical investigation of medical devices for human subjects – Part 2: Clinical investigational plan; ISO 11980:2012 Ophthalmic Optics – Contact lenses and contact lens care products – Guidance for clinical investigations; International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) and applicable local regulations. The Sponsor intends to register this clinical trial with the public database https://ClinicalTrials.gov.

[redacted]

[redacted]

[redacted]

INVESTIGATOR STATEMENT OF APPROVAL

A Study to Evaluate the Product Performance of a New Silicone Hydrogel Contact Lens

PROTOCOL

STUDY #893

I have read the attached document, concur that it contains all information necessary to conduct the study, and agree to abide by all provisions set forth therein.

I agree to conduct this study in accordance with 21CFR Parts 11, 50, 54, 56, 812, and 42 USC 282(j); and with consideration of the provision in: ISO 14155-1:2009 Clinical investigation of medical devices for human subjects – Part 1: General requirements; 14155-2:2009 Part 2: Clinical investigation of medical devices for human subjects – Part 2: Clinical investigational plan; ISO 11980:2009 Ophthalmic Optics – Contact Lenses and contact lens care products – Guidance for clinical investigations; ICH, GCPs, and applicable local regulations. I will not initiate the study until I have obtained written approval by the appropriate IRB and have complied with all financial and administrative requirements of the governing body of the clinical institution and the Sponsor. I will obtain written informed consent from each study subject prior to performing any study specific procedures.

I understand that my signature on this document indicates my agreement to this clinical Investigational Plan/Protocol and to review and, if appropriate, sign the clinical study report.

I understand that my e-signature on an electronic case report form indicates that the data therein has been reviewed and accepted by me.

I understand that this document and related information is subject to confidentiality terms found in my signed Confidentiality or Clinical Services Agreement. I agree to protect the confidentiality of my patients when allowing the Sponsor of this clinical investigation, and/or relevant regulatory authorities and IRBs, direct access to my medical records for study subjects.

_____

Principal Investigator, Printed Name

_____ _____

Principal Investigator, Signature Date

Upon signing, provide a copy of this page to Bausch + Lomb and retain a copy for your files.

PERSONNEL AND FACILITIES

NOTE: The information on this page is subject to change. All changes will be provided separately.

Sponsor
Bausch + Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609
US

Clinical Operations

Study Manager (Primary Study Contact)

Scientific & Clinical Affairs

Global Regulatory Affairs

Biostatistics

Data Management

Clinical Trial Materials

Medical Monitor (for Safety Reporting)

Pharmacovigilance (not for Safety Reporting)

SYNOPSIS

Name of Sponsor/Company: Bausch + Lomb Incorporated

Name of Investigational Product:

Test: Bausch + Lomb kalifilcon A daily disposable contact lens

Controls: Johnson & Johnson Acuvue Oasys® 1-Day with HydraLuxe™ (senofilcon A) daily disposable contact lens and Alcon DAILIES TOTAL1® (delefilcon A) daily disposable contact lenses

Title of Study: A Study to Evaluate the Product Performance of a New Silicone Hydrogel Contact Lens

Number of Clinical Centers: Approximately 35 investigative sites, United States only

Primary Objective:

The objective of this study is to evaluate the product performance of a new silicone hydrogel daily disposable contact lens, kalifilcon A, compared to the Johnson & Johnson Acuvue Oasys® 1-Day with HydraLuxe™ (senofilcon A) daily disposable contact lens and Alcon DAILIES TOTAL1® (delefilcon A) daily disposable contact lenses when worn by current soft contact lens wearers on a daily disposable wear basis.

Methodology: The study is evaluating the product performance of a new silicone hydrogel daily disposable contact lens packaged in a unique phosphate buffered solution. The silicone hydrogel contact lens infused with a unique phosphate buffered solution offers the advantage of a high oxygen material infused with ingredients for moisture retention and osmoprotection designed to promote a consistent level of health of the eye.

Approximately 800 subjects (1600 eyes) will be enrolled in this two-week, three arms, randomized, parallel, bilateral, single-masked study at approximately 35 investigative sites in the United States. The study is designed to include habitual wearers of silicone hydrogel lenses. Subjects must habitually wear Alcon's Air Optix Aqua, Air Optix with HydraGlyde, Air Optix Night & Day, Bausch + Lomb's PureVision 2, Bausch + Lomb ULTRA, CooperVision's Biofinity, Johnson & Johnson Acuvue Oasys® with HydraClear™ or Acuvue Vita soft contact lenses. Approximately one-quarter of the subjects enrolled in this study must currently wear the Alcon silicone hydrogel lenses, one-quarter of the subjects must currently wear Bausch + Lomb silicone hydrogel lenses, one-quarter of the subjects must currently wear CooperVision silicone hydrogel lenses and one-quarter of the subjects must currently wear Johnson & Johnson silicone hydrogel lenses.

At the Screening/Dispensing Visit, approximately 400 subjects will be randomized to receive Bausch + Lomb investigational kalifilcon A daily disposable contact lenses (Test), approximately 200 subjects will be randomized to receive Johnson & Johnson Acuvue Oasys® 1-Day with HydraLuxe™ (senofilcon A) daily disposable contact

lenses (Control), and approximately 200 subjects will be randomized to receive Alcon DAILIES TOTAL1® (delefilcon A) daily disposable contact lenses (Control).

Subjects will be assigned randomization numbers sequentially as they are enrolled and deemed eligible to participate. Randomization will be stratified by investigational site. Lenses will be dispensed according to randomization schedules provided to the unmasked designee at each site.

Number of Subjects Planned: Approximately 800 subjects (1600 eyes)

Diagnosis and Main Criteria for Inclusion:

- Subjects must be 18 to 40 years old on the date the ICF is signed and have capacity to provide voluntary informed consent.
- Subjects must be myopic and require lens correction from -0.50 to -6.00 Diopter (D) with 0.25 D steps, in each eye.
- Subjects must be correctable through spherocylindrical refraction and with soft spherical contact lenses to 32 letters (0.3 logarithm of the minimum angle of resolution [logMAR]) or better (2 meters distance, high-contrast chart) in each eye.
- Subjects must be free of any anterior segment disorders.
- Subjects must be adapted soft contact lens wearers and willing to wear their study lenses for at least 8 hours per day on a daily disposable wear basis for approximately 2 weeks.
- Subjects must have access to internet connection and personal email to send/receive emails.
- Subjects must habitually wear either Alcon's Air Optix Aqua, Air Optix with HydraGlyde, Air Optix Night & Day, Bausch + Lomb's PureVision 2, Bausch + Lomb ULTRA, CooperVision's Biofinity, Johnson & Johnson Acuvue Oasys® with HydraClear™, or Acuvue Vita soft contact lenses.

Key Exclusion Criteria:

- Subjects participating in any drug or device clinical investigation within 2 weeks prior to entry into this study (Screening/Dispensing Visit) and/or during the period of study participation.
- Subjects who have worn gas permeable (GP) contact lenses within the last 30 days or who have worn polymethylmethacrylate (PMMA) lenses within the last three months.
- Subjects who have any systemic or ocular disease currently affecting ocular health in the Investigator's opinion may have an effect on ocular health during the course of the study.
- Subjects using any systemic, topical or topical ocular medications that will in the Investigator's opinion, affect ocular physiology or lens performance.

[redacted]

- Subjects who currently wear daily disposable, monovision, multifocal, or toric contact lenses.
- Subjects with an refractive astigmatism of greater than 0.75 D in either eye.
- Subjects with anisometropia (spherical equivalent) of greater than 2.00 D.
- Subjects who are amblyopic.
- Subjects who have had any corneal surgery (e.g., refractive surgery).

Investigational Product, Dosage and Mode of Administration:

The investigator or designee will instruct all subjects to adhere to the Subject Instructions provided with their study contact lenses.

In order to ensure that the investigator and site staff remain masked to the study lens, an unmasked designee at each site will be responsible for all study lens accountability, including dispensation and collection of study supplies to subjects.

Subjects are to be instructed not to discuss or show the dispensed study lenses to the Investigator or masked site staff during the study.

Subjects will be instructed that other contact lenses (other than the study lenses) and contact lens care products (other than the drops provided) are not allowed to be used during the study period.

Study Duration of Treatment: approximately 2 weeks

Criteria for Evaluation:

The primary endpoints are as follows:

Effectiveness:

The primary effectiveness endpoints to be evaluated at the 2-Week Follow-Up Visit are as follows:

- Mean logMAR contact lens visual acuity at the 2-Week Follow-Up Visit
- Proportion of subjects in the Test lens group agreeing with the statement “Are comfortable throughout the day”
- Proportion of subjects in the Test lens group agreeing with the statement “Provide clear vision throughout the day”

[redacted]

- [redacted]
- [redacted]

Safety:

The primary safety endpoint will be the proportion of subjects with slit lamp findings greater than Grade 2 at any follow-up visit.

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Statistical Methods:

Continuous data will be summarized using descriptive statistics: sample size (n), mean, standard deviation (SD), median, minimum and maximum. Categorical data will be presented using the total counts for each category and corresponding percentages. The denominator for each percentage will be the number of subjects or eyes with non-missing data at the given visit for each respective study treatment, unless otherwise indicated.

Monocular contact lens logMAR visual acuity will be compared between the test lens and each comparator using a one-sided two-sample t-test and a non-inferiority margin of 0.06.

The proportions of subjects agreeing with each of two statements on the subject questionnaires will be compared to 0.5 (50%) using one-sided χ^2 tests.

The proportion of eyes with slit lamp findings greater than Grade 2 at the follow-up visit will be compared between the test lens and each comparator using confidence limits constructed using the Newcombe-Wilson score method and a non-inferiority margin of 0.05 (5%).

If the test lens is statistically successful in all primary endpoints, then the test lens will be statistically successful overall.

Sample Size Calculations:

Assuming that the test is identical in performance to each comparator for all primary endpoints, that the primary endpoints are independent, and that the assumptions used in each power calculation are correct, the overall power of the trial is greater than 90%.

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APPENDICES

LIST OF ABBREVIATIONS

Abbreviation /Acronym	Term
ADE	Adverse Device Effect
AE	Adverse Event
ASADE	Anticipated Serious Adverse Device Effect
BSCVA	Best Spectacle-Corrected Visual Acuity
CFR	Code of Federal Regulations
CRA	Clinical Research Associate
CRO	Clinical Research Organization
D	Diopter
eCRF	Electronic Case Report Form
FDA	United States Food and Drug Administration
GCPs	Good Clinical Practices
GP	Gas Permeable
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
ID	Identification
IRB	Institutional Review Board
ISO	International Organization for Standardization
ITT	Intent-to-Treat
logMAR	Logarithm of the Minimum Angle of Resolution
mm	Millimeter
OD	Right Eye
OS	Left Eye
PP	Per Protocol
PMMA	Polymethylmethacrylate
ROPI	Report of Prior Investigations
SAE	Serious Adverse Event
SD	Standard Deviation
Tel	Telephone
UADE	Unanticipated Adverse Device Effect
US	United States
VA	Visual Acuity

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

1.0 INTRODUCTION

Bausch + Lomb is evaluating the product performance of a newsilicone hydrogel contact lens packaged in a unique phosphate buffered solution. The silicone hydrogel contact lens infused with a unique phosphate buffered solution offers the advantage of a high oxygen material infused with ingredients for moisture retention and osmoprotection designed to promote a consistent level of health of the eye.

2.0 OBJECTIVE

The objective of this study is to evaluate the product performance of a new silicone hydrogel daily disposable contact lens, kalifilcon A, compared to the Johnson & Johnson Acuvue Oasys® 1-Day with HydraLuxe™ (senofilcon A) daily disposable contact lenses and Alcon DAILIES TOTAL1® (delefilcon A) daily disposable contact lenses when worn by current soft contact lens wearers on a daily disposable wear basis.

3.0 STUDY DESIGN

3.1 Description of Study Design

Approximately 800 subjects (1600 eyes) will be enrolled in this two-week, three arm, randomized, parallel, bilateral, single-masked study at approximately 35 investigative sites in the United States (US). Subjects will be assigned randomization numbers sequentially as they are enrolled and deemed eligible to participate. Lenses will be dispensed according to randomization schedules provided to the unmasked designee at each site.

At the Screening/Dispensing Visit, approximately 400 subjects will be randomized to receive Bausch + Lomb kalifilcon A daily disposable contact lenses (Test), approximately 200 subjects will be randomized to receive Johnson & Johnson Acuvue Oasys® 1-Day with HydraLuxe™ (senofilcon A) daily disposable contact lenses (Control), and approximately 200 subjects will be randomized to receive Alcon DAILIES TOTAL1® (delefilcon A) daily disposable contact lenses (Control). Subjects in all three study arms will wear the assigned lenses on a daily disposable wear basis for approximately two weeks. The lenses must be replaced with a new lens each day. Note: A new lens must be inserted/replaced whenever a lens is removed, however, this is intended to occur once each day and in general, should not occur multiple times throughout the day.

The study is designed to include habitual wearers of silicone hydrogel lenses. Subjects must habitually wear Alcon's Air Optix Aqua, Air Optix with HydraGlyde, Air Optix Night & Day, Bausch + Lomb's PureVision 2, Bausch + Lomb ULTRA, CooperVision's Biofinity, Johnson & Johnson Acuvue Oasys® with HydraClear™, or Acuvue Vita soft contact lenses. Approximately one-quarter of the subjects enrolled in this study must currently wear the Alcon ® silicone hydrogel lenses, one-quarter of the subjects must currently wear Bausch + Lomb silicone hydrogel lenses, one-quarter of the subjects must currently wear CooperVision silicone hydrogel lenses and one-quarter of the subjects must currently wear Johnson & Johnson silicone hydrogel lenses. Randomization will be stratified by investigational site.

Each subject will be required to complete an online survey after at least seven days of wearing the study lenses (and prior to their 2-week follow-up visit). Investigators will be required to complete an online investigator questionnaire at the completion of each subject's participation in the study.

3.2 Selection of Study Population

Recruitment for the study may start at any point after the Investigator agrees, in writing, to participate in the study. Written informed consent, enrollment in the study, or dispensing of study products cannot begin until the Investigator has received both Institutional Review Board (IRB) and Sponsor approval to conduct the study. The Sponsor and IRB must approve any advertising used to recruit subjects prior to use of that advertising.

All consented subjects must be accounted for, whether they participate in the study or not. Bausch + Lomb will provide a Screening Log on which to enter information for each subject who signs an Informed Consent Form (ICF). Once a potential subject is consented, the Investigator should proceed with screening procedures.

Potential subjects are deemed either "Screen Pass" or "Screen Fail". "Screen Fail" subjects are those subjects who have not met the study inclusion criteria or have met the exclusion criteria. "Screen Fail" subjects cannot participate in the study. Electronic case report forms (eCRFs) will not be completed for "Screen Fail" subjects; however, the copy of their signed ICF and any information collected as part of screening (e.g., source documents, etc.) must be kept in their permanent records.

"Screen Pass" subjects are those subjects who have met all of the study inclusion criteria and have not met any of the exclusion criteria. Only "Screen Pass" subjects are eligible to participate in the study and can be assigned to a treatment using the schedule provided to the Unmasked Designee at each site.

Once a subject is randomized (i.e., a treatment is assigned), a subject is considered active and must be accounted for at every visit until exited (completed or discontinued) from the study. Refer to Section 3.2.3 for subjects determined to be lost to follow-up.

3.2.1 Eligibility

3.2.1.1 Inclusion Criteria

1. Subjects must be 18 to 40 years old on the date the ICF is signed.
2. Subjects must be able to read, understand and provide written informed consent on the IRB approved ICF and provide authorization as appropriate for local privacy regulations.
3. Subjects must be myopic and require lens correction from -0.50 to -6.00 Diopter (D) with 0.25 D steps, in each eye.
4. Subjects must be correctable through spherocylindrical refraction and with soft spherical contact lenses to 32 letters (0.3 logarithm of the minimum angle of resolution [logMAR]) or better (2 meters distance, high-contrast chart) in each eye.
5. Subjects must be free of any anterior segment disorders.
6. Subjects must be adapted soft contact lens wearers and willing to wear their study lenses for at least 8 hours per day on a daily disposable wear basis for approximately 2 weeks.
7. Subjects must be willing and able to comply with all treatment and follow-up/study procedures, as well as willing and able to refrain from using any other contact lenses or solutions other than those provided for the duration of the study.

8. Subjects must have access to an internet connection, and have personal email to receive and send emails.
9. Subjects must habitually wear either Alcon's Air Optix Aqua, Air Optix with HydraGlyde, Air Optix Night & Day, Bausch + Lomb's PureVision 2, Bausch + Lomb ULTRA, CooperVision's Biofinity, Johnson & Johnson Acuvue Oasys® with HydraClear™, or Acuvue Vita soft contact lenses.
10. Subjects must habitually use a lens care product for cleaning, disinfection, and storage.

3.2.1.2 Exclusion Criteria

1. Subjects participating in any drug or device clinical investigation within 2 weeks prior to entry into this study (Screening/Dispensing Visit) and/or during the period of study participation.
2. Subjects who are women of childbearing potential (those who are not surgically sterilized or postmenopausal) are excluded from participation in the investigation if they meet any one of the following conditions:
   - she is currently pregnant
   - she plans to become pregnant during the study
   - she is breastfeeding
3. Subjects who have worn gas permeable (GP) contact lenses within the last 30 days or who have worn polymethylmethacrylate (PMMA) lenses within the last three months.
4. Subjects who have any systemic or ocular disease currently affecting ocular health in the Investigator's opinion may have an effect on ocular health during the course of the study.
5. Subjects using any systemic, topical or topical ocular medications that will, in the Investigator's opinion, affect ocular physiology or lens performance.
6. Subjects who currently wear daily disposable contact lenses.
7. Subjects who currently wear monovision, multifocal, or toric contact lenses.
8. Subjects with a refractive astigmatism of 0.75 D or greater in either eye.
9. Subjects with anisometropia (spherical equivalent) of greater than 2.00 D.
10. Subjects with any Grade 2 or greater finding during the slit lamp examination [redacted]. Subjects with corneal infiltrates, of ANY GRADE, are not eligible.
11. Subjects with any "Present" finding during the slit lamp examination [redacted] that, in the Investigator's judgment, interferes with contact lens wear.
12. Subjects with any scar or neovascularization within the central 6 mm of the cornea. Subjects with minor peripheral corneal scarring (that does not extend into the central area), that in the Investigator's judgment, does not interfere with contact lens wear, are eligible for this study.

13. Subjects who are aphakic.
14. Subjects who are amblyopic.
15. Subjects who have had any corneal surgery (e.g., refractive surgery).
16. Subjects who are allergic to any component in the study care products.
17. Subjects who meet any of the following criteria:
    - the subject is an employee of the investigative site
    - the subject, or a member of the subject's household, is an Ophthalmologist, an Optometrist, an Optician, or an Ophthalmic Assistant/Technician
    - the subject, or a member of the subject's household, is an employee of a manufacturer of contact lenses or contact lens care products (e.g., Alcon, Bausch + Lomb, CooperVision, Johnson & Johnson, etc.)
    - the subject, or a member of the subject's household, is an employee of a market research firm

If a subject meets all the inclusion criteria and does not exhibit any of the exclusion criteria, the subject is eligible for entry into the study. Ineligible subjects MUST NOT be enrolled in this study. Any subject enrolled in the study who later is found to have not met the eligibility criteria at entry will be discontinued.

3.2.2 Subject Completion

If a subject has no ongoing Adverse Event (AE) at the conclusion of the 2-Week Follow-up Visit, the subject should be exited from the study (per Section 5.1.3) and will be considered "Complete." Subjects who require further follow-up at the conclusion of the 2-Week Follow-up Visit will be followed by the Investigator, until the AE is resolved or stabilized. Once the AE has resolved or stabilized, the subject should be exited from the study (per Section 5.1.3) and will be considered "Complete."

A subject MAY be discontinued (at the discretion of the Investigator, the Sponsor, and/or the IRB/EC) prior to the final study visit for a variety of reasons, including, but not limited to:

- an AE occurring during the course of the study, which precludes continued treatment or follow-up
- persistent Grade 3 or 4 slit lamp findings (must be reported to the Sponsor within 24 hours)
- persistent study related symptoms/complaints
- unacceptable distance lens visual acuity (VA)
- unacceptable lens centration
- unacceptable lens movement
- other reason related to failure to follow study procedures

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

- voluntary withdrawal
- death
- Investigator decision that it is not in the best medical interest of the subject to continue participation in the investigation

- ineligible at Screening/Dispensing Visit- subject does not meet the eligibility criteria in the protocol
- inability to maintain recommended wearing schedule
- continued failure to follow subject instructions
- lack of motivation
- lost to follow-up (refer to Section 3.2.3)
- instillation of non-medically indicated solution not specified in the protocol
- if either eye is discontinued
- becomes pregnant during the study

Prior to discontinuing a subject, every effort should be made to contact the subject, schedule a final study visit, obtain as much follow-up data as possible, and to retrieve all study materials. AEs will be followed as described in Section 6.0.

Subject discontinuations will be documented clearly on the source document and applicable eCRF. The Investigator should indicate the PRIMARY (one) reason that the subject was discontinued for each eye. Subjects that are discontinued from the study following randomization will not be replaced.

The Exit Visit assessments judged as appropriate by the Investigator, should be completed for discontinued subjects.

3.2.3 Lost to Follow-up

Subjects who do not return for scheduled follow-up visits, as defined by the visit window, and cannot be contacted (following two attempts by site personnel via phone call or email), are to be considered lost to follow-up. The attempts to contact the subject should be documented and kept with the subject's source documentation.

3.3 Investigators

The study will be conducted at approximately 35 investigative sites located in the US by Investigators who are determined by Bausch + Lomb to be suitably qualified by training and experience to conduct this study. The Principal Investigator will sign the Device Investigator Agreement form prior to the start of the study. This form contains a statement specifying that the investigator is not allowed to deviate from the study protocol, except under emergency circumstances where the deviation protects the rights, safety and well-being of human subjects.

[redacted]

3.4 Study Duration

[redacted]

Subjects will be followed for approximately 2 weeks (unless discontinued or lost to follow-up) from the initial Screening/Dispensing Visit and must adhere to the following schedule:

[redacted]

Schedule of Visits

Visit	Target	[redacted]
Screening/Dispensing Visit	Day 1	[redacted]
2-Week Follow-up Visit	Day 15	[redacted]
Exit Visit	N/A	[redacted]

The visit range is based on the date the study lenses are initially dispensed (Screening/Dispensing Visit).

3.5 Protocol Changes and Amendments

Changes to the protocol will be approved by the Sponsor. An amendment to the protocol will also require submission and approval from the IRB before implementation. The Sponsor (or designee) will distribute protocol amendments to the investigative sites. The Investigator is responsible for ensuring that staff involved at his/her site complete training on the changes before implementing with subjects.

4.0 STUDY MATERIALS

Bausch + Lomb will provide all study materials (with the exception of any kits for ocular cultures) at no charge to the Investigator. [redacted] Sites will be provided with dispensing sets for the kalifilcon A (Test) and each competitor lenses (Control). All other materials will be provided to the site prior to the start of the study. [redacted] All used and unused lenses will be returned to the Sponsor at end of the study.

Subjects must use only study supplied lenses/solutions. Use of other contact lenses or care products is not allowed and will be considered a Protocol Deviation.

4.1 Description of Test Article(s) (Study Lenses)

The Test lens to be used in this study is the Bausch + Lomb kalifilcon A daily disposable contact lens, manufactured by Bausch + Lomb Incorporated, Rochester, NY. The description of the Test lens is as follows:

- Sphere Power: -0.50 to -6.00 D in steps of 0.25 D
- Diameter: 14.2 mm
- Base Curve: 8.6 mm
- Material: kalifilcon A

- Packaging Solution: Phosphate buffered solution [redacted]

4.2 Description of Comparator Product(s)

One of the Control lenses to be used in this study is the currently marketed Johnson & Johnson Acuvue Oasys® 1-Day with HydraLuxe™ (senofilcon A) daily disposable contact lenses. The description of this Control lens is as follows:

- Sphere Power: -0.50 to -6.00 D in steps of 0.25 D
- Diameter: 14.3 mm
- Base Curve: 8.5 mm
- Material: senofilcon A
- Packaging Solution: Buffered saline solution with methyl ether cellulose.

The other Control lens to be used in this study is the currently marketed Alcon DAILIES TOTAL1® (delefilcon A) daily disposable contact lens. The description of this Control lens is as follows:

- Sphere Power: -0.50 to -6.00 D in steps of 0.25 D
- Diameter: 14.1 mm
- Base Curve: 8.5 mm
- Material: delefilcon A
- Packaging Solution: Phosphate buffered saline solution with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic) acid.

4.3 Instructions for Use and Administration

Test or Control lenses will be worn on a daily disposable wear basis. New study lenses will be dispensed at the Screening/Dispensing Visit in sufficient quantities to maintain a daily disposable wear modality for the duration of the study. Subjects must wear their study lenses to the 2-Week Follow-up Visit. After contact lens assessments are complete at the 2-Week Follow-up Visit, the unmasked designee from the study site will collect and store worn lenses for subsequent return to the Sponsor.

4.3.1 Storage Requirements

All Test and Control lenses provided by the Sponsor must be stored in a secure location accessible only to unmasked study personnel and maintained at room temperature above 34°C (1°F).

4.3.2 Subject Instructions

a) All subjects must be given Subject Instructions for the use of study lenses (refer to Appendix C for Subject Instructions). Subjects must comply with the instructions provided to them. Subject Instructions will be supplied to the Investigator by Bausch + Lomb (or Clinical Research Organization [CRO]) for distribution to the subject.

b) The Investigator or other designee must review, with the subject, the Subject Instructions and the precautions and warnings, as appropriate for the study.

c) Any subject who does not follow instructions to a degree that, in the Sponsor or Investigator's opinion, jeopardizes the subject's well-being or the validity of the study, should be discontinued.

4.3.3 Fitting Guide

The Investigator should refer to the Fitting Guide (see Appendix D) for fitting the Test and Control lenses.

4.4 Other Study Materials

All subjects will be dispensed Bausch + Lomb Sensitive Eyes® Drops for use as needed and lens cases for return of worn study lenses to the Investigator during the study. Subjects are not to use their own contact lens drops/solutions, but rather the drops/solutions provided to them. ***OTHER CONTACT LENS CARE PRODUCTS ARE NOT ALLOWED TO BE USED.***

Investigators will return worn and unworn study lenses to the Sponsor at the end of the study.

4.5 Packaging and Labeling

The Test lenses will be packaged in a blister pack with an investigational label. The label will contain the following information at minimum:

- lens power
- base curve
- lot number
- expiration date
- manufacturer's name
- manufacturer's place of business
- caution statement

Control lenses will be packaged in standard commercial blister pack packaging.

4.6 Accountability

The unmasked designee at each site will be responsible for keeping current and accurate records of the amount of study lenses received and dispensed, and their disposition. The study lenses must be stored under the appropriate conditions in a secure area and are to be dispensed only to subjects enrolled in the study, in accordance with the conditions specified in this protocol. A Product Accountability Log will be provided to the sites for the unmasked designee to maintain records of the study lenses assigned to each enrolled subject.

At the completion of the study, the Sponsor/Sponsor's representative will review and verify the Investigator's accountability records. Following verification, and as directed by the Sponsor, all study lenses (Test and Control, both worn and unworn) must be returned to the Sponsor [redacted]

[redacted]

4.7 Masking/Unmasking

The Investigator/site staff and Bausch + Lomb personnel or designee(s) involved in the conduct of the study will be masked to the study lenses. Each site must have an unmasked designee that will be responsible for dispensing and collecting the study Test and Control lenses and for performing accountability. This designee shall not participate in clinical assessments after the subject has been randomized.

The randomization schedule will be created by an unmasked statistician [redacted] Personnel involved with repackaging and supply of clinical trial material will also be unmasked. Field Clinical Research Associates (CRAs) will become unmasked during product reconciliation, at the conclusion of each site's participation in the study, and prior to locking the database. Unmasked designees at the site will manage the dispensation and return of study lenses and related supplies. All other study personnel will remain masked until database lock.

In the event that unmasking of a subject's randomly assigned treatment is required, the Investigator (or other designee) is required to contact the Medical Monitor (or designee) to request permission to unmask. The Medical Monitor (or designee) will contact the Sponsor study manager and obtain approval to grant permission to unmask. Upon receipt of authorization from the Sponsor study manager, the Medical Monitor (or designee) will advise the Investigator (or other qualified designee) to obtain the treatment assignment from the unmasked designee. If the Medical Monitor cannot be contacted, the Investigator (or other qualified designee) should then contact the Sponsor designee who can authorize the unmasking of a subject. In the event that the Medical Monitor or Sponsor designee cannot be contacted and the Investigator (or other qualified designee) deems the unmasking necessary the Investigator may confer with the unmasked designee, without authorization and unmask the subject. Whether unmasking occurs inadvertently or intentionally, the Investigator must notify the Medical Monitor or Sponsor designee as soon as possible after unmasking. In addition, the Investigator must record the date, time, and reason for unmasking the study treatment in the source documentation.

Subjects will be instructed to insert the study lenses out of the sight of the Investigator or site staff other than the unmasked designee. Subjects are not to show the study blister packs and foils to the Investigator or site staff other than the unmasked designee, unless instructed to do so.

4.8 Product Replacement

Subjects will be given an adequate supply of study lenses to wear on a daily disposable basis for the duration of the study.

Should the site's inventory be low or depleted, additional inventory of lenses (either Test or Control) can and must be ordered [redacted]

4.9 Risk Assessment

Information concerning potential risks associated with the investigational device (as well as possible interactions with concomitant medical treatments and risk-to-benefit ratio) can

be found within the Report of Prior Investigations (ROPI) for the study. Risks are also summarized within the Informed Consent document. The assessments required for the study are routinely performed and are standard of care for contact lens wearers. The subjects will be informed of any potential study specific risks in the ICF or if new risks become apparent during the study.

5.0 STUDY METHODS

5.1 Study Visits

Refer to Appendix A for a schedule of visits and parameters and Appendix B for methods of clinical evaluation.

Following identification of a potential subject, the Investigator (or designee) will explain the purpose of the study, procedures, risks/benefits, and subject responsibilities to the potential subject. The subject's willingness and ability to meet the follow-up requirements of the study will be determined. If the subject chooses to participate in the investigation, written informed consent will be obtained. The subject and the person obtaining written consent will sign and date the IRB-approved ICF. The Investigator must keep the signed ICF document. The signed original document should be retained in the subject's records, and a copy should be provided to the subject. In addition, the applicable privacy regulation requirements must be met.

5.1.1 Screening/Dispensing Visit (Day 1)

A Screening Log will be provided by the Sponsor to track all consented subjects that the Investigator interviews regarding the study. Once all available lines on the Screening Log have been completed, or the Investigator has fulfilled his/her quota of subjects, the Investigator will sign and date the form to verify that all the subjects who interviewed for the study have provided informed consent and Health Insurance Portability Accountability Act (HIPAA) authorization.

After obtaining written informed consent, prospective subjects will be screened to determine whether they meet the entry criteria for the study.

Screening/Dispensing will proceed as follows:

a. Enter the subject information on the next available line of the Screening Log.

b. Collect the subject's demographics.

c. Collect the following lens use history information from the subject:

- [redacted]

d. Collect ocular medical history (within 1 year of signing the ICF) and concomitant medications. Concomitant medications (as defined for this study) include any

medications for ocular conditions taken within 30 days of signing the ICF and any concomitant medications taken during the study.

e. Perform high-contrast distance VA with the subject's habitual lenses.

f. [redacted] .

g. Perform the following assessments (without lenses):

- spherocylindrical refraction using a phoropter
- distance high-contrast best spectacle-corrected visual acuity (BSCVA) using a phoropter
- keratometry

h. Perform a slit lamp examination (without lenses) and record:

- Any ungraded finding marked as "Present"
- Any corneal scars
- Any neovascularization within the central 6 mm of the cornea
- Any corneal staining
- Any corneal infiltrate (record details on the Corneal Infiltrates Evaluation Form in Section 8.0 of Appendix B)
- Record and sketch any scars and slit lamp findings greater than Grade 2 in the subject's source document
- After fluorescein is used, flush the eyes with sterile saline solution. Wait at least 5 minutes before inserting new lenses.

i. Indicate on the Screening Log whether the subject is a "Screen Pass" or "Screen Fail".

Only "Screen Pass" subjects should be randomized in the study. If the subject is a "Screen Pass", perform the following:

j. Randomize the subject using the Randomization Schedule provided to the unmasked designee at each site. Dispensation will be stratified by investigative site.

The unmasked designee will then dispense lenses (in the subject's randomized study lens assignment and appropriate sphere power) to maintain a daily disposable modality until the 2-Week Follow-up Visit and record the dispensation in the Product Accountability Log.

In an effort to ensure the Investigator remains masked, the unmasked designee MUST dispense the lens blister packs.

k. Have the subject insert one pair of the study lenses in their eyes. In an effort to ensure the Investigator remains masked, the subject MUST insert the lenses out of the sight of the Investigator and other masked site personnel.

l. Review Subject Instructions with the subject and provide the subject with a copy of the instructions. Dispense two lens cases. Instruct the subject to place all worn lenses in a lens case [redacted] Remind the subject to bring all lenses [redacted] to the 2-Week Follow-up Visit.

[redacted]

NOTE: Study lenses should be allowed to equilibrate a minimum of three minutes on the eye.

m. Record the dispensed lens sphere power and after a minimum of three minutes of the subject wearing the lenses, perform the following assessments:

- distance high-contrast lens VA
- over-refraction and distance high-contrast VA (using a phoropter)
- lens wettability
- lens centration
- lens movement

For each eye, compare the distance high-contrast lens VA to the distance high-contrast BSCVA obtained at this visit. If the VA has decreased by 5 letters (0.1 logMAR) or more, explain.

n. Collect abbreviated Lens Performance Rating Scales regarding the study lenses [redacted]:

- [redacted]

o. The site will enter subject ID and contact information [redacted] **immediately** after the Screening/Dispensing Visit. **This information will not be available to anyone via data export. The subject will be able to login via phone app or computer to complete the survey.** This should be done only for randomized subjects.

p. Internet Survey Instructions will be given to the subject. Remind the subject to complete the online survey after at least 7 days (but prior to 2-week Follow-Up Visit) of wearing study lenses. [redacted]

Note: If the subject is discontinued or exited at this visit (after randomization), complete the "Exit Visit" and collect any AEs (per Section 5.1.3).

5.1.2 2-Week Follow-up Visit (Day 11-17)

NOTE: The online survey should be completed by the subject after a minimum of 7 days of wear but before the subject comes into the office for the 2-Week Follow-up Visit.

NOTE: If the subject does not come to a visit wearing lenses and is not experiencing any problems, it is preferred if the current visit is rescheduled within the visit window.

a. Obtain information on any changes in ocular medical history and/or the use of concomitant medications.

b. Collect the following lens information from the subject:

- [redacted]

[redacted]

c. Perform the Lens Performance Rating Scales [redacted] from the subject regarding their study lenses

d. Collect Symptom/Complaints information [redacted].

e. Evaluate the study lenses (while on eye) and record the following assessments:

- distance high-contrast lens VA
- over-refraction and distance high-contrast VA (using a phoropter)
- lens wettability
- lens deposits
- lens centration
- lens movement

For each eye, compare

- The distance high-contrast lens VA to the distance high-contrast lens VA obtained at the Screening/Dispensing Visit.
- The distance high-contrast lens VA to the distance high-contrast BSCVA obtained at the Screening/Dispensing Visit.
- If the VA has decreased by ≥ 10 letters (0.2 logMAR) or more, explain.

e. Perform a slit lamp examination (without lenses) and record the following:

- Any ungraded finding marked as "Present"
- Any new corneal scars
- Any neovascularization within the central 6 mm of the cornea
- Any increase in grading of corneal staining
- Any corneal infiltrate [redacted]
- Record and sketch any scars and slit lamp findings greater than Grade 2 in the subject's source document.
- After fluorescein is used, flush the eyes with sterile saline solution. Ensure that at least 5 minutes pass if the subject inserts a new pair of lenses at this visit.

f. Investigator fill out the Investigator Questionnaire

g. The unmasked designee will collect all worn and unworn lenses from the Subject for return to the Sponsor. Record the collection in the subject's Product Accountability Log.

h. Collect/assess all AEs/ADEs, including serious or significant non-serious AEs.

i. The following eCRF should be completed:

- 2-Week Follow-up Visit

5.1.3 Exit Visit

(To occur on the same day immediately following the 2-Week Follow-Up Visit or Unscheduled Visit for any subject(s) being discontinued from the study or subjects being followed beyond 2 weeks for ongoing AE)

Do not continue with the Exit Visit until/unless the subject is ready to exit the study. Subjects who require further follow-up due to an AE at the conclusion of the 2-Week Follow-Up Visit will be followed according to the AE and/or Unscheduled Visit Section until the AE is resolved or stabilized.

a. Obtain information on any changes in ocular medical history and/or the use of concomitant medications.

b. Indicate status of the subject on the Subject Exit Form. If the status is "Discontinued" or "Non-dispensed," indicate the PRIMARY exit reason for each eye on the Subject Exit Form.

c. For all subjects, complete an exit ocular examination without lenses on the eyes. Collect the following assessments:

   – spherocylindrical refraction using a phoropter
   – distance high-contrast BSCVA using a phoropter
   – keratometry

d. For each eye, compare the Exit Visit distance high-contrast BSCVA to the distance high-contrast BSCVA obtained at the Screening/Dispensing Visit. [redacted]

e. For each eye, compare the Exit Visit (horizontal and vertical) keratometry readings to the Screening/Dispensing Visit (horizontal and vertical) keratometry readings. If [redacted]

f. The unmasked designee will collect all worn and unworn lenses from the Subject for return to the Sponsor. Record the collection in the subject's Product Accountability Log.

g. The following eCRF should be completed:

   – Subject Exit

5.1.4 Market Research Surveys

5.1.4.1 Online Consumer Survey

Each subject will be required to complete a Subjective Assessment through an internet survey. Each enrolled subject will be provided with an internet address to access ***after at least 7 days of lens wear (but prior to the 2-week follow-up visit)***. Each subject will be provided with a confidential unique ID and password (login) in order to access the online survey. If the user forgets their password, there will be a "forgot password" option within the system. The system will send reminders to the subject via email or mobile alerts. The study coordinator will call the subject prior to the visit date to remind the subject to complete the survey.

There will be a specified timeframe in which the survey must be completed. The Investigator will provide the market research firm with the subject's email address. If the subject has not completed the survey during the specified duration, the market research firm will contact that subject by email with a reminder to complete the survey. If the subject has not completed the survey by the time of the 2-week Follow-up visit the subject may complete it at that time.

[redacted]

5.1.4.2 Investigator Questionnaire

The Investigator (or designee) will complete a survey to answer questions about each subject's study lens wear at the subject's exit visit. This information will be collected within the eCRF system.

5.1.5 Unscheduled Visits

Additional visits may be scheduled, as necessary, to ensure the safety and well-being of subjects. All additional exams should be fully documented in the source documents and on Unscheduled Visit eCRFs, as appropriate. Visits intended to fulfill scheduled visit requirements that fall outside the designated scheduled visit range are not Unscheduled Visits. In these cases, the visit data will be collected and transcribed to the appropriate scheduled visit eCRF.

[redacted]

Subjects who require further follow-up on an AE/SAE upon discontinuation or at the conclusion of the 2-Week Follow-Up Visit will be followed according to the AE and/or Unscheduled Visit Section as necessary. At these follow-up visits, the subject should remove contact lenses s/he may be wearing. Assessments will be performed according to the investigator's judgement. The Investigator is required to follow the subject until the condition no longer warrants further follow-up for study purposes.

Product Dispensing Only (Part of the Unscheduled Visit - used only if lens replacement is needed)

If a subject is only seen for an unscheduled lens replacement, a complete exam is not required as long as the subject is not experiencing any problems. In these cases, the following information will be collected in the source documents and transcribed to the Product Dispensing Only eCRF:

- Visit date
- Subject Identification (ID) number
- Subject initials
- Primary reason for replacement

NOTE: For study lens replacement, an unmasked designee MUST dispense the study lens blister packs to the subject to ensure the Investigator remains masked. The unmasked designee will also record the lenses dispensed on the Product Accountability Log. If the subject inserts lenses at the visit, the subject MUST insert the lenses out of the sight of the Investigator and other masked site staff.

If a subject is experiencing problems, complete the following, as appropriate, and complete an Unscheduled Visit eCRF instead of a Product Dispensing Only eCRF:

a. Indicate the reason for the Unscheduled Visit.

[redacted]

b. Obtain information on any changes in ocular medical history and/or the use of concomitant medications.

c. Collect the following lens information from the subject regarding the study lenses:

- [redacted]

d. If the subject did not come to the visit wearing one or more study lenses, go to step g. Otherwise, evaluate the lenses (while on eye), and record the following assessments:

- distance high-contrast lens VA
- over-refraction and distance high-contrast VA (using a phoropter)
- lens wettability
- lens deposits
- lens centration
- lens movement

For each eye, compare the distance high-contrast lens VA to the distance high-contrast lens VA obtained at the Screening/Dispensing Visit. [redacted]

For each eye, compare the distance high-contrast lens VA to the distance high-contrast BSCVA obtained at the Screening/Dispensing Visit. [redacted]

e. Perform the Lens Performance Rating Scales [redacted] from the subject regarding their study lenses

f. Collect Symptoms/Complaints information [redacted]

g. Perform a slit lamp examination (without lenses) and record the results and findings. Record and sketch any scars and slit lamp findings greater than Grade 2 in the subject's source document.

g. If an unscheduled lens replenishment is required, the unmasked designee will dispense additional lenses ensuring that the subject has sufficient lenses to maintain a daily disposable wear modality until the Follow-Up Visit according to the Randomization assignment for each subject and record in the Product Accountability Log.

h. Record the following in the source documentation and transcribe to the appropriate eCRF form for the Unscheduled Visit:

- dispensed lens sphere power

i. If a lens parameter change is required, the subject MUST insert one pair of the dispensed lenses in their eyes. After the lenses have equilibrated for at least 3 minutes, confirm the lenses are acceptable for study continuation. If the lenses are unacceptable for study continuation, complete the "Exit Visit" (per Section 5.1.3) and discontinue the subject from the study.

j. The unmasked designee will collect the worn lenses from the Subject (if brought by the subject to the Unscheduled Visit) and record the collection in the Product

Accountability Log. If additional lenses are dispensed, record the dispensation in the Product Accountability Log. Dispense additional lens cases, if needed. Instruct the subject to place all worn lenses in a lens case (10 pairs of lenses per case) with no solution (dry). The subject should return the lens cases to the site at the 2-Week Follow-Up Visit.

k. Collect/assess all AEs/ADEs, including serious or significant non-serious AEs.

l. The following eCRFs should be completed:

- Unscheduled visit

Note: If the subject is discontinued or exited at this visit, complete the "Exit Visit" (per 5.1.3).

5.1.6 Missed Visits

If a subject misses the scheduled follow-up visit, the visit is considered missed. Indicate a missed visit on the eCRF for that scheduled visit. Schedule the subject for an Exit Visit as soon as possible. If subject can't be reached or can't be rescheduled, the subject should be recorded as Lost to Follow up.

5.2 Study Completion

Bausch + Lomb will notify the Investigator when to contact the IRB to inform them that the study is complete.

5.2.1 Study Termination/Suspension

If, during the study, it becomes evident to the Sponsor that the study should be stopped prematurely or placed on hold, appropriate notification will be given to the Investigator(s) and IRBs, and the United States Food and Drug Administration (FDA) or Local Health Authority, as applicable. Bausch + Lomb will instruct the Investigators to stop/restart dispensing study materials and will arrange for study closeout, if applicable, at each site.

5.3 Concomitant Medications/Therapy

Other contact lenses/solutions are not allowed to be used by subjects during the study.

Ocular medications or systemic or topical medications that, in the Investigator's opinion, could potentially affect ocular physiology or lens performance are prohibited during the course of the study. Use of prohibited medications will be documented in the Exit CRF form.

5.4 Protocol Deviations

The date of and reason for deviations will be documented in all cases. Significant or major protocol deviations impacting the safety of the subject or the integrity of the study must be reported by the Investigator to the IRB immediately. Reporting of all other protocol deviations must adhere to the requirements of the governing IRB.

Any subject enrolled in the study who later is found to have not met the eligibility criteria at entry will be discontinued. Otherwise, unless the protocol deviations put the subject at risk or the subject's condition requires that they be discontinued from the study, subjects may continue to participate until the end of the study.

According to the Device Investigator Agreement, all investigators participating in this study agree to conduct the study in accordance with the relevant, current protocol and agree to only make changes in a protocol after being notified by the Sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

Site Corrective Action plans will be developed and completed as deemed necessary by the CRO for sites or investigators who deviate from this protocol in a way that adversely affects the rights, safety or well-being of the subject(s) and/or the quality or integrity of data. The Site Corrective Action Plan will outline the deviation and the site's corrective and/or remedial actions. Decisions regarding critical deviations that merit investigator disqualification and site closure will be made by the Sponsor and documented in the Trial Master File.

6.0 ADVERSE EVENTS

6.1 Adverse Event Definitions

For the purposes of this study, reportable AEs include ocular AEs and non-ocular serious adverse events (SAEs). All AEs will be classified first for seriousness and significance and then as to whether or not the AE is device related or non-device related. If the AE is assessed as device related, then the AE will be classified as an adverse device effect (ADE). ADEs will then be further classified as an anticipated serious adverse device effect (ASADE) or an unanticipated adverse device effect (UADE). AEs, ADEs, ASADEs, UADEs, SAEs, Significant Non-Serious AEs and Non-Significant Non-Serious AEs are defined as follows:

6.1.1 Adverse Event (AE)

Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in a subject, user, or other persons, whether or not related to the investigational medical device. This definition includes events not related to the investigational medical device, comparator, or the procedures involved. For users or other persons, this definition is restricted to events related to investigational medical devices.

Throughout the course of this study all efforts will be made to remain alert to reportable AEs. If an AE occurs, the first concern will be the safety of the subject and appropriate medical intervention will be made.

All reportable AEs occurring after signing of informed consent and through the subject's end of participation in the study must be reported. All reportable AEs must be followed until the event resolves or stabilizes.

Applicable AEs (from slit lamp examination) should be photo documented and communicated to the Medical Monitor.

6.1.2 Adverse Device Effect (ADE)

An ADE is an AE that is assessed to be related to the use of an investigational medical device. This definition includes AEs resulting from insufficient or inadequate instructions for use; deployment, implantation, installation, or operation; or any malfunction of the investigational medical device. This definition also includes any event resulting from use error or from intentional misuse of the investigational medical device.

6.1.2.1 Anticipated Serious Adverse Device Effect (ASADE)

An ASADE is an ADE that first meets the Serious Adverse Event criteria [redacted] and which, by its nature, incidence, severity or outcome, has been previously identified in the investigational plan or application (including a supplementary plan or application) and/or in the risk analysis report. ASADEs include:

- Corneal Ulcer (infectious or non-infectious)
- Keratitis
- Sensitivity to light (photophobia)
- Excessive eye secretions including mucopurulent discharge
- Blurred vision, rainbows or halos around objects
- Poor visual acuity (reduced sharpness of vision)
- Moderate to severe eye pain not relieved by removing the lens

6.1.2.2 Unanticipated Adverse Device Effect (UADE)

A UADE is an ADE that first meets the Serious Adverse Event criteria (see Section 6.1.3) and has an effect on health or safety or any life-threatening problem or death caused by, or associated with, a device if that effect, problem or death was not previously identified in nature, severity or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

6.1.3 Serious Adverse Event (SAE)

An AE that:

- Led to death;
- Led to serious deterioration in the health of the subject, that resulted in:
  - A life-threatening illness or injury; or
  - A permanent impairment of a body structure or a body function (e.g., blindness); or
  - Inpatient or prolonged hospitalization; or
  - Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function;
- Led to fetal distress, fetal death, or a congenital abnormality or birth defect.

Note: A planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered an SAE.

Serious adverse events are also those events that result in, or have potential to cause, either permanent impairment of an ocular function or damage to an ocular structure and may necessitate medical or surgical intervention.

Serious adverse events may include any hazardous, sight-threatening conditions occurring after exposure to the test article, including the following:

- A presumed infectious ulcer (defined as a progressive erosion of the corneal tissue). For the purposes of reporting, this includes:

- Central or para-central location;
- Penetration of Bowman's membrane;
- Infiltrate ≥2 mm diameter;
- Associated with iritis;
- Associated with any increase in intraocular pressure;
- Culture positive for microorganisms;
- Increasing size or severity at subsequent visits;

NOTE: Signs of a presumed infectious corneal ulcer may include irregular focal infiltrates, active lesions with raised edges, significant diffuse infiltration, anterior corneal to mid-stromal involvement, erosion with overlying staining, conjunctival and lid edema, anterior chamber reaction (iritis), and severe bulbar and limbal redness. Symptoms associated with a presumed infectious ulcer (microbial keratitis) may include pain of rapid onset, severe redness, purulent or mucopurulent discharge, tearing, and photophobia.

- Any central or paracentral (within 6 mm of cornea) corneal event that results in permanent opacification (such as corneal scar or vascularization);
- Any serious adverse ophthalmic events including hypopyon and/or hyphema;
- Any neovascularization within the central 6 mm of the cornea;
- Permanent loss of ≥ 2 lines/10 letters of BSCVA;
- All cases of iritis.

6.1.4 Significant Non-Serious Adverse Events

A significant non-serious adverse event is an AE that does not meet the serious criteria, is considered significant by the Sponsor, and requires expedited reporting. These events include:

- Peripheral non-progressive non-infectious corneal ulcers;
- All symptomatic corneal infiltrative events;
- All cases of corneal staining greater than or equal to Grade 3;
- A temporary loss of two or more lines/10 or more letters of BSCVA (for greater than or equal to 2 weeks);
- Neovascularization cases Grade 2 or greater;
- Any ocular event that necessitates temporary lens discontinuation of greater than or equal to 2 weeks.

6.1.5 Non-Significant Non-Serious Adverse Events

A non-significant non-serious adverse event may include but are not limited to the following and does not require expedited reporting:

- Bacterial Conjunctivitis;
- Viral Conjunctivitis;

- Allergic Conjunctivitis;
- Corneal Edema;
- Contact Lens Related Papillary Conjunctivitis; and,
- Loss of Contrast Sensitivity

6.2 Adverse Event Treatment and Culturing

With any AE, treat the subject as appropriate to prevent further complications and to potentially resolve the event consistent with the standard of care.

For purposes of this study, the Sponsor requests that cultures should be obtained in cases of corneal ulcer or suspected ocular infection, unless medically contraindicated. Cultures should be taken from the cul-de-sac, lower eyelid margin, and the corneal lesion (if applicable). [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

6.3 Evaluations

When evaluating for reportable AEs, the Investigator must first determine if the event is serious (refer to Section 6.1.3 for criteria) and/or significant (refer to Sections 6.1.4 and 6.1.5) and then assess the severity of symptoms and the relationship of the event to the study device using the following guidelines:

6.3.1 Severity

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

6.3.2 Relationship to Study Device

- **Related:** There is at least a reasonable possibility that the AE is related to the study device (contact lens). Reasonable possibility means that there is evidence to suggest a causal relationship or association between the study device and the AE. Also referred to as an ADE.

- **Not Related:** There is little or no reasonable possibility that the AE is related to the study device (contact lens). This assessment implies that the AE has no evidence to suggest either a causal relationship or association to the study device and a more likely or certain alternative etiology exists.

6.4 Procedures for Reporting SAEs and Significant Non-Serious Adverse Events

An AE classified as an SAE or a Significant Non-Serious AE requires expeditious handling and reporting to the Sponsor to comply with regulatory requirements, as follows:

- The event must be reported to the Medical Monitor (or designee) within 24 hours of the Investigator's awareness of the event via facsimile/email transmission on a paper SAE or Significant Non-Serious AE Report Form signed by the Investigator.

[redacted]

- [redacted]
- Investigators should not wait to receive additional information to fully document the event before initially notifying the Medical Monitor (or designee) of an SAE or a Significant Non-Serious AE. Additional relevant information such as hospital records and autopsy reports should be provided to the Medical Monitor (or designee) as soon as they are available.
- The Investigator should take all appropriate measures to ensure the safety of the subjects: notably, he/she should follow a subject with an SAE or Significant Non-Serious AE until the event has resolved or the condition has stabilized. This may imply that follow-up will continue after the subject has left the study, and that additional evaluations may be requested by the Sponsor.
- Ensure that the subject's identity is protected and the subject's identifiers in the clinical trial are properly mentioned on the form.
- BEGIN TREATMENT OF THE AE IMMEDIATELY BY A SUITABLY LICENSED EYE CARE PROFESSIONAL.
- Continue to update the paper SAE or Significant Non-Serious AE Report Form, if applicable, each time the subject is seen during the management of the event and at resolution of the event. All updated report forms should be submitted to the Medical Monitor (or designee) who will distribute the reports as stated above. Whenever possible, it is suggested that the Investigator take photographs of all applicable AEs and forward them to the Medical Monitor (or designee).

- Events requiring medical treatment will be evaluated by the Sponsor. Upon review of the medical treatment, Bausch + Lomb representatives may contact the Investigator to request further information concerning the treatment.
- [redacted]
- [redacted]
- [redacted]

6.4.1 Off-site Unanticipated Adverse Device Effect Reporting

When participating in multicenter clinical investigations, Investigators may receive off-site UADE reports. These are Sponsor reports of UADEs which occurred at other clinical sites for the same trial, or in different trials using the same test or control lenses, that met the criteria for reporting to a regulatory agency. [redacted]

6.4.2 Reporting Device Deficiencies

A device deficiency is defined as an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. Device deficiencies include malfunctions, use errors, and inadequate labeling.

Investigators must evaluate, record, and report via applicable forms any complaints/ deficiencies or malfunctions experienced during this trial to the Medical Monitor (or designee) promptly. The Sponsor and Medical Monitor shall review all device deficiencies and, upon the Sponsor's request, Investigators must supply any additional information related to the safety reporting of a particular event.

[redacted]

6.4.3 Guidelines for Reporting Pregnancies

All female subjects of childbearing potential must use an effective method of birth control during the study, to include 2 weeks after last visit, in a manner such that risk of contraceptive failure is minimized. Abstinence is allowed as a birth control method.

During the study, all female subjects of childbearing potential should be instructed to contact the Investigator immediately if they suspect they might be pregnant (e.g., missed or late menstrual period). Female subjects who become pregnant during the study will be discontinued from the study and followed until completion of pregnancy. Every effort will be made to obtain the health status of the mother and infant at term or fetus (in cases of miscarriage or therapeutic abortion). Pregnancy itself is not considered an AE.

[redacted]

All pregnancies will be followed until outcome even after study closure. [redacted]

Although pregnancy occurring in a clinical study is not considered to be an AE or SAE, any pregnancy complication, spontaneous abortion, or elective termination of a pregnancy for medical reasons, will be recorded as an SAE. [redacted]

[redacted]

7.0 STATISTICAL METHODS

7.1 Study Endpoints

7.1.1 Primary Effectiveness Endpoints

- Mean logMAR contact lens visual acuity at the 2-Week Visit
- Proportion of subjects in the Test lens group agreeing with the statement “Are comfortable throughout the day”
- Proportion of subjects in the Test lens group agreeing with the statement “Provide clear vision throughout the day”

[redacted]

[redacted]

7.1.4 Primary Safety Endpoint

The primary safety endpoint will be the proportion of subjects with slit lamp findings greater than Grade 2 at any visit.

[redacted]

7.2 Hypotheses

7.2.1 Contact Lens Visual Acuity (VA)

The null hypothesis (H_0) is that the difference in mean logMAR VA between the test lens and the comparator lens ($\mu_T - \mu_C$) is equal to or greater than 0.06. The alternative hypothesis (H_1) is that the difference is less than 0.06.

$$H_0: \mu_T - \mu_C \geq 0.06$$

$$H_1: \mu_T - \mu_C < 0.06$$

7.2.2 Proportions of Subjects Agreeing

For each of these endpoints, the null hypothesis (H_0) is that the proportion of subjects in each lens group agreeing with the statement (π) is less than or equal to 0.5 (50%). The alternative hypothesis (H_1) is that the proportion is greater than 0.5.

$$H_0: \pi \leq 0.5$$

$$H_1: \pi > 0.5$$

7.2.3 Slit Lamp Findings

The null hypothesis (H_0) is that the difference in the proportion of eyes with any slit lamp finding greater than Grade 2 between the test group and the comparator group ($\pi_T - \pi_C$) is 0.05 or more. The alternative hypothesis (H_1) is that the difference is less than 0.05.

$$H_0: \pi_T - \pi_C \geq 0.05$$

$$H_0: \pi_T - \pi_C < 0.05$$

7.3 Sample Size

For the purpose of estimating power, it is assumed that 5% of the subjects will exit the study prior to the primary analysis visit.

As is customary for contact lens studies, the two eyes of each subject will be treated as independent sampling units. Consequently, the power calculations for lens visual acuity and slit lamp findings are completed using the number of eyes rather than the number of subjects.

7.3.1 Contact Lens Visual Acuity

When the sample sizes in the groups are 760 and 380 eyes, a two group one-sided 0.05 significance level t-test will have greater than 99% power to reject the null hypothesis that the test is inferior to the standard in favor of the alternative hypothesis that the treatment is non-inferior, assuming that the expected difference in means is 0, a non-inferiority margin of 0.06 and the common standard deviation is 0.07.

7.3.2 Proportions of Subjects Agreeing

7.3.2.1 Test Lens Group

A one group χ^2 test with a 5% one-sided significance level will have greater than 99% power to detect the difference between the Null hypothesis proportion, π_0, of 0.5 and the Alternative proportion, π_1, of 0.86 when the sample size is 380 subjects.

7.3.2.2 Comparator Lens Groups

A one group χ^2 test with a 5% one-sided significance level will have greater than 99% power to detect the difference between the Null hypothesis proportion, π_0, of 0.5 and the Alternative proportion, π_1, of 0.86 when the sample size is 190 subjects.

7.3.3 Slit Lamp Findings

With 380 eyes in the control group and 760 eyes in the test group, the upper limit of the observed one-sided 95% confidence interval will be expected to be less than 0.05 with greater than 99% power when the Standard proportion, π_0, is 0.01 and the Test expected proportion, π_1, is 0.01; results are based on 100 simulations using the Newcombe-Wilson score method to construct the confidence interval. (Newcombe RG (1988) Interval estimation for the difference between independent proportions: comparison of eleven methods. Statistics in Medicine 17:873-890.)

7.3.4 Overall Power and Enrollment Targets

7.3.4.1 Overall Power

Assuming that the test is identical in performance to each comparator for all primary endpoints, that the primary endpoints are independent, and that the assumptions used in each power calculation are correct, the overall power of the trial is greater than 90%.

7.3.4.2 Enrollment Target

To allow for up to 5% losses prior to the primary analysis time point, the enrollment targets will be

- 400 subjects (800 eyes) in the test (Bausch + Lomb kalifilcon A) group
- 200 subjects (400 eyes) in each of the comparator groups

The total enrollment target will be approximately 800 subjects (1600 eyes).

7.4 Randomization

Subjects will be randomly assigned to the three treatment groups in a 2:1:1 ratio (Bausch + Lomb kalifilcon A: Johnson & Johnson Acuvue Oasys® 1-Day with HydraLuxe™: Alcon DAILIES TOTAL1®(delefilcon A). Randomization will be stratified by site.

7.5 Study Populations

7.5.1 Intent-to-Treat (ITT) Population

The ITT Population will include all randomized subjects. Summaries of the ITT Set will include subjects in their randomized treatment group.

7.5.2 Per Protocol (PP) Population

The PP Population will include all ITT Population subjects without major protocol deviations.

7.5.3 Safety Population

The Safety Population will include all subjects who were dispensed study lenses. Summaries of the Safety Set will include subjects in the treatment group corresponding to the treatment they actually received.

7.6 Statistical Analysis

7.6.1 Methods of Analysis

7.6.1.1 General Methods

Continuous data will be summarized using descriptive statistics: sample size (n), mean, standard deviation (SD), median, minimum and maximum. Categorical data will be presented using the total counts for each category and corresponding percentages. The denominator for each percentage will be the number of subjects or eyes with non-missing data at the given visit for each respective study treatment, unless otherwise indicated.

[redacted]

7.6.1.2 Primary Endpoint Analysis

Each primary effectiveness endpoint hypothesis will be evaluated using the ITT Population and will be evaluated again using the PP Population as a sensitivity analysis.

[redacted]

7.6.1.2.1 Contact Lens Visual Acuity

Visual acuity will be reported as letters read correctly. The letters read will be converted to logMAR acuity, which will be summarized using continuous summary statistics by treatment group. The test lens will be compared to each of the two comparators. The primary analyses will be conducted using eye level data. A two-sample t-test will be used to estimate the difference between treatment groups and a one-sided upper 95% confidence limit for the difference. If the confidence limit is less than or equal to 0.06 for the comparison to each comparator, then the test lens will be statistically successful in this endpoint.

7.6.1.2.2 Proportions of Subjects Agreeing

Subjects will respond to each statement with one of the following responses.

- Strongly agree
- Agree
- Slightly agree
- Slightly disagree
- Disagree
- Strongly disagree

For each endpoint, responses will be classified as either "Top 3 Boxes" (strongly agree, agree, slightly agree) or "Bottom 3 Boxes" (slightly disagree, disagree, strongly disagree). The proportion of subjects in each lens group in the Top 3 Boxes category will be summarized and compared to 0.5 using a one-sided χ^2 test. If the P-value is less than 0.05 for the Test lens group, then the Test lens will be statistically successful in this outcome.

7.6.1.2.3 Slit Lamp Findings

At each follow-up visit, graded slit lamp findings will be assessed for each eye using Grades 0 through 4. Using only the non-missing observations from all visits without imputation, each eye will be classified with respect to findings greater than Grade 2 at any visit (Absent, Present). Missing data will not be imputed. Greater than Grade 2 findings (Absent, Present) will be summarized at the eye level by treatment using categorical summary statistics for the Safety Set in a table. A one-sided upper 95% confidence limit around the difference in "Present" proportions between the test and control treatment groups will be constructed using the Newcombe-Wilson score method. If the upper confidence limit is less than 5%, then the null hypothesis that the Test lens is not non-inferior will be rejected, and the Test lens will be statistically successful in this outcome.

7.6.1.3 Definition of Statistical Success

If the test lens is statistically successful in all primary endpoints, then the test lens will be statistically successful overall.

7.6.2 Subject Demographics and Baseline Characteristics

Subject demographics and baseline characteristics will be summarized by treatment group and overall.

7.6.3 Subject Disposition

Subject disposition (completed, discontinued) will be summarized categorically, as will the reasons for discontinuation.

7.6.4 Protocol Deviations

Important (major) protocol deviations will be summarized by category and treatment group for the ITT Population in a table.

Categories of important protocol deviations will include the following, which will be derived via data entered on the case report forms.

- Ineligibility
- Not dispensed study treatment
- Misrandomization
- Dispensing of the incorrect lens (type or prescription)
- Use of medications that could potentially affect the primary effectiveness endpoint
- Failure to comply with the procedures used to assess the primary effectiveness endpoint, such as missing a scheduled visit or failing to complete the procedure in accordance with instructions

Additional important protocol deviation categories may be added prior to unmasking.

Important (major) protocol deviations will also be displayed in a listing.

[redacted]

[redacted]

7.6.7 Missing Data

Missing data will not be imputed.

7.6.8 Multiple Comparisons

Success in all primary endpoint comparisons is required for statistical success, so no adjustment for multiple comparisons is required.

7.6.9 Interim Analyses

No interim analyses are planned.

8.0 DATA QUALITY ASSURANCE

8.1 Study Monitoring

Bausch + Lomb representatives must be allowed to visit all study site locations to assess the data, quality, and study integrity in a manner consistent with applicable health authority regulations and the procedures adopted by Bausch + Lomb.

[redacted]

Prior to the start of the study, member(s) of Bausch + Lomb (or designees) will review the protocol, eCRF, regulatory obligations, and other material or equipment relevant to the conduct of the study with the Investigator/Sub-Investigator and relevant study site personnel.

Monitoring visits and telephone consultations will occur as necessary, or per the monitoring plan, during the course of the investigation to verify the following:

- the rights and well-being of subjects are protected
- the conduct of the investigation is in compliance with the currently approved protocol/amendment, 21CFR Parts 11, 50, 54, 56, 812, and 42 USC 282(j); and with consideration of the provisions in: ISO 14155-1:2011 Clinical investigation of medical devices for human subjects – Part 1: General requirements; 14155-2:2011 Part 2: Clinical investigation of medical devices for human subjects – Part 2: Clinical investigational plan; ISO 11980:2012 Ophthalmic Optics – Contact lenses and contact lens care products – Guidance for clinical investigations; ICH, GCPs, and applicable local regulations
- the integrity of the data, including adequate study documentation
- the facilities remain acceptable
- the Investigator and site personnel remains qualified and able to conduct the study
- study lenses accountability (at the conclusion of each site's participation)

During the course of the study, if the Sponsor determines that an Investigator is not compliant with the protocol and/or applicable regulatory requirements, the Sponsor will take action to secure compliance. In addition, the Sponsor may terminate the Investigator's participation in the study if appropriate, or if the Investigator remains non-compliant despite the Sponsor's actions.

Full details for site monitoring procedures will be outlined in the Monitoring Plan.

8.2 Source Documentation

All medical information obtained at each study visit must be recorded in the subject's record (source documentation) in real time as it is collected. Source documentation consists of original subject documents, as well as data and records with information relevant to the subject and his/her participation in the study.

Examples of source documents include: hospital records, clinical and office charts, laboratory notes, memoranda, signed ICF, evaluation checklists, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, and information initially recorded in an electronic format. Source documentation worksheets may be provided by the Sponsor to record pertinent information. Data captured by the market research group is not considered source documentation.

Subject completed forms are also considered to be source data. In no instance should an Investigator or study site personnel record any data or make changes to subject completed forms. The Investigator or designee should review subject completed forms during study visits for completeness and accuracy. If an entry is found to be illegible or a mistake is found (e.g., incorrect year was recorded), the subject should be instructed to edit the entry

by drawing a single line through the original entry, entering the new information, and dating and initialing the change.

[redacted]

Subject data required by this protocol are to be transferred from the source to the eCRFs. The Investigator and his/her study site personnel will be responsible for completing the eCRFs. The Investigator is required to verify that all of the requested information is accurately recorded on the eCRFs by providing an electronic signature. All information requested on the eCRFs needs to be supplied, including but not limited to, subject identification, date(s), assessment values, etc., and any omission or discrepancy will require explanation. All information on eCRFs must be traceable to source documents. Market research data will be collected via ePRO and processed according to the policies and procedures of the market research group. The data will not be included on eCRFs or verified by Bausch + Lomb.

The study monitor will be responsible for reviewing and verifying the data recorded on the eCRFs per the study Monitoring Plan, utilizing the original source documentation and will query discrepant findings. The Investigator and study site personnel will be responsible for answering all queries.

Details regarding procedures used for data review, database cleaning and issuing and resolving queries will be outlined in the Monitoring Plan and Data Management Plan.

A copy of the complete subjects' eCRFs for the site will be provided to the Investigator at the conclusion of the study, who must ensure that it is stored in a secure place.

8.4 Recording of Data and Retention of Documents

The subject will only be identified by the subject number and by their initials if also required. Confidentiality of subject records must be maintained to ensure adherence to applicable local privacy regulations.

[redacted]

[redacted]

8.5 Auditing Procedures

Audits of clinical research activities in accordance with the Sponsor's internal Standard Operating Procedures to evaluate compliance with the principles of GCP may take place. A regulatory authority may also wish to conduct an inspection (during the study or after its completion). If an inspection is requested by a regulatory authority and/or IRB, the Investigator must inform the Sponsor immediately that this request has been made.

8.6 Institutional Review Board

The Investigator should ensure their participation in the study, in addition to the protocol, subject recruitment materials (written information or materials including web pages, radio advertisements, television spots or written text developed to encourage subject enrollment) and the ICF to be used in this study are approved by their institution's IRB, or if not using their institution's IRB, approved by the reviewing central IRB prior to entering any subjects in the study. Documentation of IRB approval of the study protocol and informed consent must be provided to the Sponsor prior to initiation of the study. In addition, the Investigator must ensure that the reviewing IRB has provided approval for any protocol amendments prior to implementation. If the amendment necessitates a revision to the ICF, the Investigator should ensure the revised form is also submitted to and approved by the Sponsor and the IRB and implemented as directed.

8.7 Publication of Results

All study data generated as a result of this study will be regarded as confidential, until appropriate analysis and review by the Sponsor or its designee and the Investigator(s) are completed. The results of the study may be published or presented by the Investigator(s) after the review by, and in consultation and agreement with the Sponsor, and such that confidential or proprietary information is not disclosed.

Prior to publication or presentation, a copy of the final text should be forwarded by the Investigator(s) to the Sponsor or its designee, for comment. Such comments shall aim to ensure the scientific integrity of the proposed publications and/or presentations and ensure that the data and material referring to Bausch + Lomb products and activities receive fair, accurate, and reasonable presentation.

The Sponsor may also choose to submit the results of this study for publication.

8.8 Statements of Compliance

8.8.1 Ethics Review

The final protocol, including the final version of the Subject Instructions and Informed Consent Form, must be approved by an IRB before enrollment of any subject into the study. The Principal Investigator (or Sponsor/CRO on behalf of the Principal Investigator) is responsible for informing the IRB of any amendment to the protocol as per local requirements. Any additional requirements imposed by the IRB shall be followed.

8.8.2 Ethical Conduct of the Investigation

The study will be performed in accordance with the ethical principles that have their origin in the most recent version of the Declaration of Helsinki, and with applicable regulatory requirements. Subjects who are close colleagues, associates or family members of, or in any way dependent on the Sponsor or the investigator, will not be included in this study.

8.8.3 Informed Consent Process

The Principal Investigator will ensure that each subject is given full and adequate oral and written information about the nature, purpose, possible risks and benefits of the study. Subjects must also be notified that they are free to discontinue participation in the study at any time. The subject should be given the opportunity to ask questions and time for consideration.

The subject's signed informed consent must be obtained before conducting any study related procedures. The original must be filed by the investigative site. A copy of the signed Informed Consent Form should be given to the subject. If modifications are made to the Informed Consent Form, the new version must be approved by the IRB. The new version of revised Informed Consent Form(s) must be reviewed and signed by all active (if required by the IRB) and new subjects at the first opportunity after approval by the IRB.

[redacted] [redacted]

[redacted] [redacted] [redacted]

APPENDIX A: SCHEDULE OF VISITS AND PARAMETERS

All study tasks should be performed by qualified study site personnel as indicated on the delegation of authority log under the supervision of the Principal Investigator.

PROCEDURE/ASSESSMENTS		Screening/Dispensing Visit Day 1	2-Week Follow-up Visit (Day 11-17)	Exit
Informed Consent/HIPAA Authorization		X		
Demographics		X		
Contact Lens Use History and Contact Lens Use[c] (e.g., average daily wear time, # of days worn, lens brand, lens care system brand, wear modality, product use history)		X	X	
Ocular Medical History and Concomitant Medications		X	X	X
High-contrast distance VA (with habitual lenses)		X		
Eligibility		X		
Randomization		X		
Dispense Study Materials		X		
Return Worn /Unworn Lenses, blister foils and Study Materials			X	X[e]
Study Lens Performance Scales (VAS;100-point scales)[a]		X[d]	X	
Symptoms/Complaints rating scales			X	
Remind subject to complete online survey form after minimum 7 days of wear but prior to the 2-Week Follow-up Visit.		X		
Adverse Events		X	X	
To be performed **without** study lenses	Spherocylindrical refraction	X		X
	Distance BSCVA	X		X
	Keratometry	X		X
	Slit Lamp Exam	X	X	
Lens Performance dispensed		X		
To be performed **with** study lenses	Distance lens VA	X	X[b]	
	Over-refraction and distance VA	X	X[b]	
	Lens Wettability	X	X[b]	
	Lens Deposits		X[b]	
	Lens Centration	X	X[b]	
	Lens Movement	X	X[b]	
Investigator Questionnaire			X	

[a] Use the Lens Performance Rating Scales included in initial study shipment.; [b] To be assessed only for lenses worn to the visit.;[c] Contact lens use history is taken at the Screening Visit and contact lens use is taken at the Follow-Up Visit;[d] Lens Performance Rating Scales at Screening Visit are to be recorded with habitual lenses and again (abbreviated) with study lenses; at least 3-minutes following insertion of study lenses;[e] If the exit visit is prior to 2-Week Follow-up

APPENDIX B: METHODS OF CLINICAL EVALUATION

Maintenance and calibration of the equipment relevant to study assessments must be appropriately performed and documented by the investigative site, where applicable. Any changes to the procedures described in this appendix will be provided under separate cover.

1.0 Visual Acuity/Refraction

It is essential that a standard procedure be used to obtain VA measurements. The VA and refraction measurements should be obtained by a physician, optometrist, or trained technician. One standard logMAR chart, high 90% contrast, with Sloan letters will be used to obtain the VA measurements in this study. The following VA equipment from Precision Vision, Inc. will be used in this study: 90% High Contrast 6.5 feet (2.0 meters) testing distance Translucent Chart (CAT. NO. 2103-2), and the Precision Vision Small Illuminator Cabinet (CAT. NO. 914).

1.1 Illumination of the logMAR Chart and Room Illumination

The internal illumination of the logMAR chart should be turned on. This will provide the nominal contrast for each of the charts. **Room illumination should be turned off**, to ensure that the illumination is consistent for each measurement. Ambient sources of light in the room, such as computer monitors, should be turned off or covered. A small source of illumination may be used to allow recording of data and to ensure that it is not difficult or dangerous for staff or subjects to move around the testing area, but these light sources should not be placed so that they are directed toward the subject during testing. The room lighting and any ambient sources should be consistent in their use and placement at each subject visit throughout the course of this study.

1.2 Determination of High Contrast Visual Acuity

The subject should be seated so that the distance from the subject's eyes to the logMAR chart is 6.5 feet (2.0 meters). The chart should be at eye level for the subject. The logMAR charts have two alternative letter sequences from 28 letters (0.3 logMAR) to 62 letters (-0.3 logMAR). It is recommended that one letter sequence is used for the right eye, and the second letter sequence is used for the left eye, to minimize learning effects at each visit. Care should be taken to completely occlude the eye not being measured.

Since the test distance of the chart is not at optical infinity, refractive power compensation is required to simulate optical infinity. **The VA should be measured through the phoropter using the distance refractive correction with the addition of +0.50 D to compensate for the reduced test distance of 6.5 feet (2.0 meters).**

If all letters are correctly identified on any given line, then the subject is encouraged to read the next smaller line. When the subject says they cannot read a letter, they should be required to guess. A maximum effort should be made to identify each letter. A scoring sheet for each eye is provided to keep track of the letters correctly identified by writing an "X" over the incorrectly identified letter. The subject continues reading down the chart to the last letter of a given line, **until the subject has missed 3 letters on a line with 5 letters**. The incorrect letters can occur at the beginning, middle, or end of this line and do not have to be consecutive.

1.3 Recording and Scoring logMAR Values

Using the Sponsor supplied recording/scoring sheet, an example of which is shown below, the tester will record the actual VA measurement.

The number of letters CORRECT will be recorded on the recording/scoring sheet in the far right box on the corresponding line. The lines will then be added up and the "TOTAL" number of letters correctly identified will be recorded on the recording/scoring sheet. The "TOTAL" is the number that will be entered onto the eCRF.

Example of Distance VA:

In the example below, all letters in lines 1 through 8 were read correctly. Line 9 had 4 correct responses, and line 10 had only 1 correct response. After line 10, the VA test would be considered complete. In this example, the total letters correctly identified is 42. This number is recorded in the space marked "TOTAL" and also recorded on the eCRF.

Distance Visual Acuity (High Contrast)				
Snellen	**logMAR**	**Chart**		**Letters Correct**
20/160	0.9	S Z N		3
20/125	0.8	R N C V		4
20/100	0.7	K C R H N		5
20/80	0.6	Z K D V C		5
20/63	0.5	H V O R K		5
20/50	0.4	R H S O N		5
20/40	0.3		K S V R H	5
20/32	0.2		H N K C D	5
20/25	0.1		N D V K O	4
20/20	0		X X O X X	1
20/16	-0.1		V R N D O	
20/12.5	-0.2		C Z H K S	
20/9.5	-0.3		O R Z S K	

TOTAL	42

2.0 Slit Lamp Examination

The following parameters will be assessed during the Slit Lamp Examination (without lenses):

Epithelial Edema

0 - None: No epithelial or sub-epithelial haziness. Normal transparency.
1 - Trace: Barely discernible localized epithelial or sub-epithelial haziness.
2 - Mild: Faint but definite localized or generalized epithelial haziness.
3 - Moderate: Significant localized or general epithelial haziness.
4 - Severe: Definite widespread, epithelial cloudiness giving dull glass appearance to cornea, or numerous coalescent buliae.

Epithelial Microcysts

0 - None: No microcysts seen using retroillumination.
1 - Trace: Fewer than 50 microcysts over central or para-central cornea. No overlying staining or surface anomaly.
2 - Mild: More than 50 microcysts over central or paracentral cornea. No overlying staining or surface anomaly.
3 - Moderate: More than 50 microcysts, tending to be coalescent and accompanied by overlying faint staining or dry spots.
4 - Severe: Numerous, dense, coalescent microcysts accompanied by overlying significant staining or erosion.

Corneal Staining

Corneal staining must be assessed after the instillation of fluorescein. If needed, a Wratten Gel Filter will be provided by the Sponsor for the evaluation of corneal staining. The Wratten Gel Filter must be used as a barrier filter in the observation pathway, in combination with the cobalt blue filter.

0 - None: No fluorescein staining.
1 - Trace: Minimal superficial staining or stippling, and non-coalescing. Includes superficial foreign body staining.
2 - Mild: Lightly coalescent or diffuse punctate staining, with no stain diffusion into stroma.
3 - Moderate: Significant or densely coalescent punctate staining, including slight diffusion of stain into stroma.
4 - Severe: Severe abrasion or erosion with loss of epithelial substance. Marked and rapid diffusion of stain into stroma.

Limbal Injection

0 - None: No hyperemia present. Normal appearance of limbal vessels including prominent limbal vascular arcades.
1 - Trace: Very slight hyperemia of limbal vessels in one quadrant.
2 - Mild: Mild hyperemia of limbal vessels in more than one quadrant.
3 - Moderate: Marked hyperemia of limbal vessels in any quadrant.
4 - Severe: Marked hyperemia of limbal vessels in all quadrants.

Bulbar Injection

0 - None: No hyperemia present. Normal appearance of conjunctival vessels.
1 - Trace: Slight hyperemia of conjunctival vessels in one quadrant.
2 - Mild: Mild hyperemia of conjunctival vessels in more than one quadrant.
3 - Moderate: Marked hyperemia of conjunctival vessels in any quadrant.
4 - Severe: Marked hyperemia of conjunctival vessels in all quadrants.

Upper Lid Tarsal Conjunctival Abnormalities

0 - None: Normal, velvet tarsal conjunctival appearance. No hyperemia or enlarged papillae.
1 - Trace: Slight tarsal conjunctival hyperemia with slight loss of smoothness.
2 - Mild: Slight tarsal conjunctival hyperemia with slight loss of smoothness. Noticeable enlargement of papillae, but less than 1.0 mm in diameter.
3 - Moderate: Definite loss of smoothness with enlarged papillae, but less than 1.0 mm in diameter with marked tarsal conjunctival hyperemia.
4 - Severe: Localized or generalized giant papillae, larger than 1.0 mm in diameter and/or severe tarsal conjunctival hyperemia.

Corneal Neovascularization

0 - None: Normal appearing limbus, including prominent limbal vascular arcades.
1 - Trace: Vascularization less than 1.5 mm of advancement into cornea in one quadrant.
2 - Mild: Vascularization less than 1.5 mm of advancement into cornea in more than one quadrant.
3 - Moderate: Vascularization 1.5 mm to less than 2.5 mm of advancement into cornea in any quadrant.
4 - Severe: Vascularization more than 2.5 mm of advancement into cornea in any quadrant.

Corneal Infiltrates

0 - No infiltrates.
1 - Single infiltrate; (focal and peripheral), asymptomatic.
2 - Single or multiple infiltrate(s); with injection and/or associated symptoms.
3 - Single or multiple infiltrate(s); injection with overlying corneal defect(s).
4 - Single or multiple infiltrate(s); injection with diffusion of stain into stroma.

New corneal scar or pre-existing corneal scar

Absent or Present

Location:

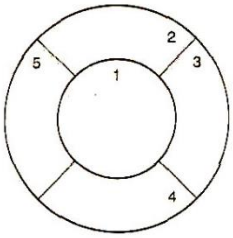
Check all that apply

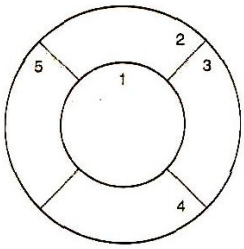
□ Central (central 6 mm, 3 mm from corneal center)

- □ Nasal
- □ Inferior
- □ Temporal
- □ Superior

Size: X.X (mm)

Draw:





Absent or Present

New Corneal Scar
Corneal Striae
Conjunctivitis
Other Anterior Segment Abnormalities
External Adnexa Abnormalities

3.0 Method for the Examination, Description and Classification of Lens Deposits and Wettability

Introduction:

The following procedure has been developed to assist in the examination, description, and classification of wettability and deposits found on contact lenses in the Investigator's office.

Materials needed:

Slit Lamp

Procedure:

Each lens should be examined on the eye using the slit lamp employing a 7X to 15X magnification.

Classify the deposit and record findings at applicable visits as follows:

I. Type of Deposit

Indicate the most prominent lens surface deposit found [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

II. Estimated Percentage of Lens Surface Covered By Deposits

Estimate the percentage of the lens surface that is covered by deposits [redacted]:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

III. Degree of Deposit

Indicate the degree of the deposit on the lens surface [redacted]:

- [redacted]
- [redacted]
- [redacted]

IV. Wettability

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

4.0 Method for the Examination, Description and Classification of Lens Fit at all Visits

The following procedure has been developed to assist in the examination, description, and classification of contact lenses fit at all visits in the Investigator's office.

Materials needed: Slit Lamp

Procedure: Each lens should be examined on the eye using the slit lamp employing a 7X to 15X magnification.

Lens fit will be assessed utilizing the scales below:

I. Lens Centration

[redacted]

Qualitative Lens Centration

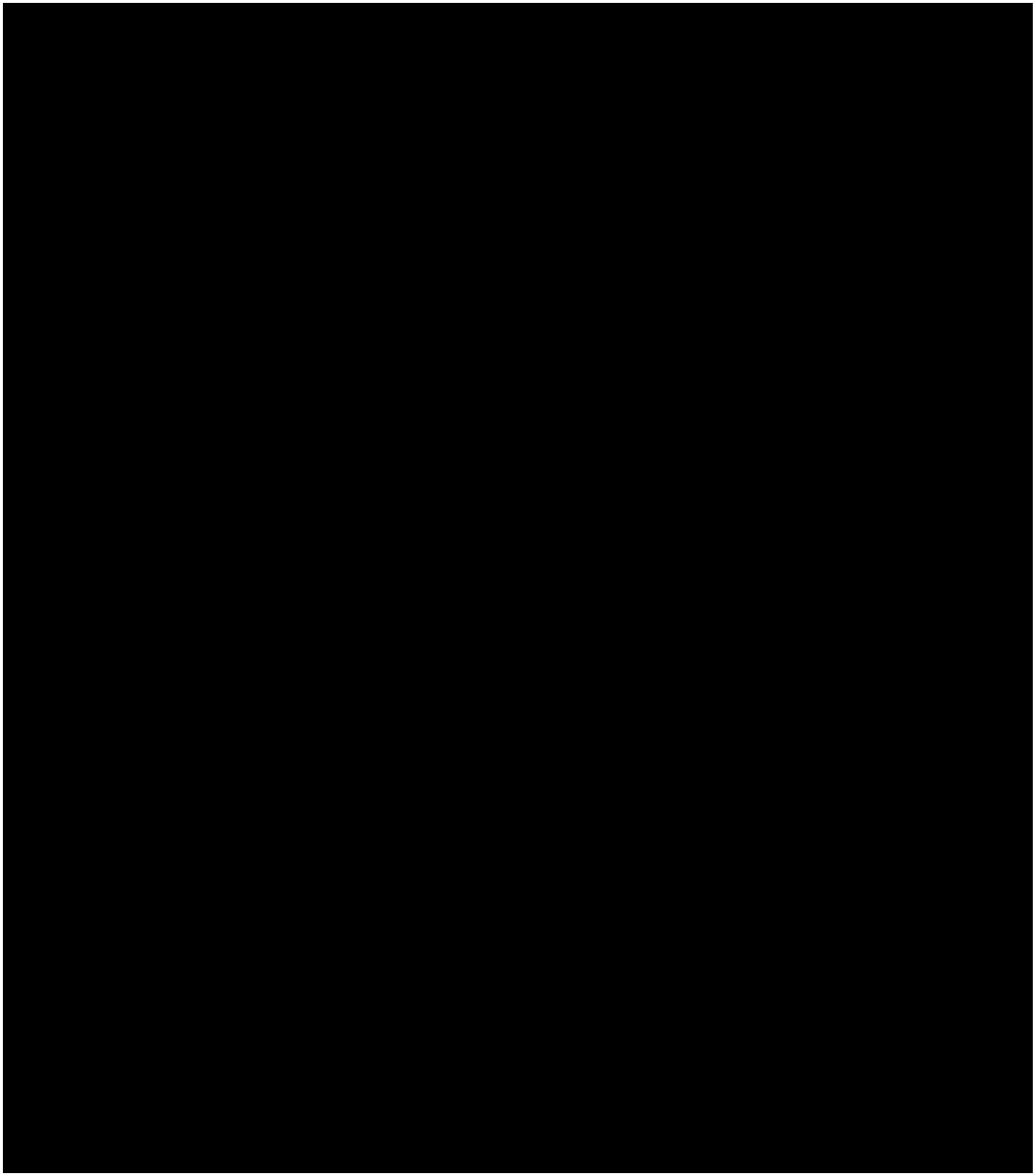
- [redacted]
- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- [redacted]

[redacted]

II. Lens Movement

- As the subject blinks normally, observe lens movement, [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

BAUSCH + LOMB™



5.0 Symptoms/Complaints Rating Scales

For completion of the Symptoms/Complaints Rating Scale Form (conducted at applicable visits with the Test or Control lenses), the Investigator or designee will obtain Subject responses [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted]

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

6.0 Len Performance Rating Scales

[redacted]

7.0 Investigator Questionnaire

[redacted]

[redacted]

8.0 Culture Procedures

NOTE: The site must use their standard of care culture kit and ship specimens to their local laboratory for testing per the local lab's required procedures. Hard copy results must be filed in the subject record and entered into the eCRF.

PROCEDURES FOR THE INVESTIGATOR

A. In the case of corneal ulcer or suspected ocular infection, the cul-de-sac, lower lid margin, and the corneal lesion (if applicable) of the affected eye must be cultured.

1. **Cul-de-sac Culture**
   a. The swab from a culture collection kit is moistened in sterile, physiological saline solution, with no preservatives.
   b. The ocular specimen is obtained by holding the lids open and asking the subject to gaze upward. The moistened swab should be drawn across the cul-de-sac while rotating the swab 360 degrees around the axis of the stick. Care should be taken to avoid contact of the swab with the lashes and the lid margins.
   c. Place the swab in the transport tube media according to manufacturer's directions.
   d. Repeat steps a through c using a separate swab and a separate tube of transport media for the other eye if both eyes require culturing.
2. **Eyelid Culture**
   a. The swab from a culture collection kit is moistened in sterile, physiological saline solution, with no preservatives.
   b. The specimen is obtained from the margin of the lower lid by drawing the swab along the margin of the lid.
   c. Place the swab in the transport tube media according to manufacturer's directions.
   d. Repeat steps a through c using a separate swab and a separate tube of transport media for the other eye if both eyes require culturing.
3. **Corneal Culture**
   a. The swab from a culture collection kit is moistened in sterile, physiological saline solution, with no preservatives.
   b. The specimen is obtained from the corneal lesion by rotating the swab on the lesion for 10 seconds.
   c. Place the swab in the transport tube media according to manufacturer's directions.
   d. Repeat steps a through c using a separate swab and a separate tube of transport media for the other eye if both eyes require culturing.

B. Labeling and Transportation of Cultures to the Clinical Laboratory:

1. Complete the requisition supplied by your laboratory included with the culture collection kit. Affix labels supplied in the culture collection kit to the ocular specimens as well as to the container used to transport the contact lens case (which contains the contact lens[es] and contact lens case solution) if available.
2. The specimens, contact lens(es), lens case(s), lens case solution(s) and report form are then sent to the local laboratory under refrigerated conditions using the supplies provided by your laboratory.

9.0 Corneal Infiltrates Evaluation Form

[redacted]

APPENDIX C: SUBJECT INSTRUCTIONS

FOR SINGLE-USE DISPOSABLE WEAR

CAUTION: Investigational Device. Limited by Federal law (U.S.A.) to investigational use.

INTRODUCTION

You will participate in this study designed to evaluate the product performance of an investigational daily disposable contact lens (Test) when compared to the currently marketed the Johnson & Johnson Acuvue Oasys® 1-Day with HydraLuxe™ (Control) and Alcon DAILIES TOTAL1® (delefilcon A) (Control). As a participant in this study, you will be randomly assigned to wear either the Test or Control lenses on a daily disposable basis. Study lenses will be dispensed at the Screening/Dispensing Visit. **It is very important that you do not use any other contact lenses or solutions other than those dispensed to you during the study.**

You will wear the lenses on a daily disposable basis and replace the lenses daily but **do not discard your worn lenses** as they will be collected at your 2-Week follow-up visit. Throughout the study, place all worn lenses in a study lens case that was provided to you (up to 10 pairs of lenses per case) with no solution (dry). You will return the lens cases to the office at your 2-Week Follow-Up visit/Exit visit. Bring all lenses (worn in lens cases and unworn blister packs) and blister foils to the 2-Week follow-up visit/Exit visit or any unscheduled visit.

Do not discuss or describe your contact lenses with anyone except the person who gave you the study lenses at the Screening/Dispensing Visit. You should **not** show the study blister packs and foils to the Investigator or site staff unless instructed to do so.

Please keep all appointments and follow these instructions thoroughly. If you have any questions or problems, call your study doctor at _____.

Note: Please schedule your 2-Week Follow-up Visit at the Screening/Dispensing Visit.

Follow-Up Visit Schedule

Visit	Day/Month/Year	Time
2-Week Follow-Up	/ /	_____

Note: Wear your study lenses to your follow-up visit.

For this study, you will be using the following products:

- Bausch + Lomb Sensitive Eyes® Drops (to be used if needed).
- Lens cases for storage of worn study lenses (up to 10 pairs of lenses, stacked dry).

[redacted]

GENERAL INFORMATION

Do NOT use any products other than those dispensed to you by your study doctor for use in this study.

If problems or symptoms should occur, immediately remove your lenses and follow the steps described in the sections of these instructions entitled ***Warnings*** and ***Adverse Effects***. Prompt attention to problems is essential and may require immediate professional care.

Remember, when wearing contact lenses, your eyes should look and feel good and your vision should be clear.

Because they are worn directly on your eyes, contact lenses affect the way in which your eyes function. These effects tend to increase with the length of time the lenses remain on your eyes between removals. Although the great majority of people successfully wear contact lenses without problems, before you decide whether to continue wearing contact lenses for daily disposable wear, you should discuss with your study doctor the effects of contact lenses on your eyes and the risks associated with wearing contact lenses. You also should read the sections of these instructions entitled "Warnings", "Adverse Reactions", "Precautions", and "Wearing Restrictions and Indications". Ask your study doctor to explain anything that you do not understand, including any additional restrictions which may be given to you by your study doctor. These contact lenses have been prescribed for single-use disposable wear and should be replaced each time lenses are removed from your eyes.

You also need to remember that soft contact lenses, including those covered by these instructions, are made of a type of plastic that absorbs liquids, vapors and small particles, and for some people, may collect deposits from your natural eye fluids. Therefore, you should strictly follow these instructions and any other instructions given to you by your study doctor. Any failure to follow these instructions and the wearing restrictions will increase the chances of contamination, damage to the lenses, or a buildup of deposits on the lenses, which can lead to serious, sight-threatening eye infections and injuries.

Adherence to your prescribed wearing schedule and regular check-up visits to your study doctor are also necessary for the proper and safe use of contact lenses. Soft contact lenses generally are comfortable from the beginning. Therefore, be sure to follow the wearing schedule prescribed for you, and do not over wear your lenses simply because they remain comfortable and you are not experiencing a problem. Only your study doctor, through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.

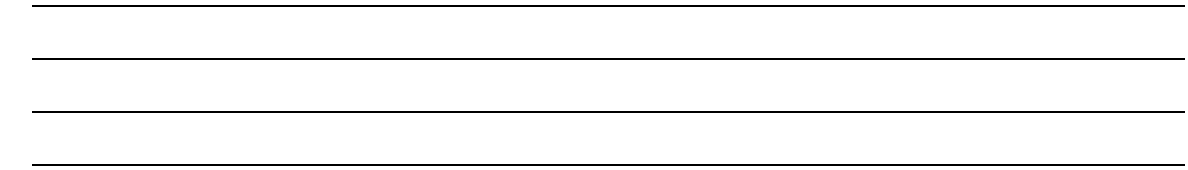
Finally, if problems or symptoms should occur, immediately remove your lenses and follow the steps described in the section of these instructions entitled "Warnings and Adverse Reactions." Prompt attention to problems is essential and may require immediately professional care.

Remember, when wearing soft contact lenses your eyes should look and feel good, and your vision should be clear.

1. WEARING RESTRICTIONS and INDICATIONS

The lenses have been prescribed for single-use disposal wear and will be replaced after each removal.

- Keep a spare pair of lenses and a lens case available in case you have to remove your lenses immediately upon the appearance of a problem or symptom.
- Do not use aerosol products such as hair spray while wearing your lenses. The lenses may absorb the spray, resulting in injury to the eye and damage to the lens.
- Avoid wearing the lenses around fumes, irritating vapors, smoky or dusty conditions. The lenses may absorb the chemicals or particles, resulting in injury to the eye.
- Avoid rubbing your eyes with the lenses in, which can irritate the eye or dislodge the lens.
- If you get something in your eye, remove the lens immediately. Do not replace with new lens until your eye feels normal.
- Tell your regular physician and every other doctor that you visit, that you wear contact lenses and the type of lenses that you wear. If you are admitted to a hospital, also tell your nurses that you wear contact lenses.
- A bottle of Bausch + Lomb Sensitive Eyes® Drops will be dispensed to you at the Screening/Dispensing Visit. You may use these drops **as needed** throughout the study. Your Study Doctor can provide you with additional drops should you need a new bottle.
- Do not use any eye drops, ointments, or medicines in your eye unless they are specifically approved by your study doctor or physician. Some drops, ointments, or medicines will cause injury to the eye if used by a contact lens wearer.
- Ask your study doctor whether there are any other wearing restrictions that apply to you, write those restrictions in the spaces provided below and follow them carefully.



2. WARNINGS

You should be aware of and fully discuss with your study doctor the following warnings pertaining to contact lens wear:

- Problems with contact lenses could result in serious injury to your eye. It is essential that you follow your study doctor's direction and all labeling instructions for proper use of lenses. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily disposable lenses are not indicated for overnight wear, and you should not wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when daily disposable lenses are worn overnight.
- Strict compliance with your wearing restrictions, wearing schedule, and follow-up visit schedule should be followed.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should immediately remove lenses and promptly contact your study doctor.

3. PRECAUTIONS

You should be aware of and fully discuss with your study doctor the following safety precautions:

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting your lenses.
- If the lens sticks (stops moving), you should use the Bausch + Lomb Sensitive Eyes® Drops rewetting drops provided to you for this study. The lens should move freely on your eye for the continued health of your eye. If non-movement of the lens continues, you should immediately consult your study doctor. Do not attempt to remove the lens, except on the instructions of your study doctor.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in your eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with your fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.
- Carefully follow these handling, insertion, and wearing instructions for the daily disposable contact lenses and those instructions prescribed by your study doctor.
- Never wear lenses beyond the period recommended by your study doctor.
- Always handle lenses gently and avoid dropping them.
- Ask your study doctor about wearing lenses during water activities and other sports.

- Inform your doctor (health care professional) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with your fingernails.
- Always contact your study doctor before using any medicine in your eyes.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Your study doctor should provide you with a recommended follow-up schedule.

4. ADVERSE REACTIONS (Problems And What To Do)

You should be aware that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain,
- Comfort is less than when lens was first placed on eye,
- Abnormal feeling of something in the eye (foreign body, scratched area),
- Excessive watering (tearing) of the eyes,
- Unusual eye secretions,
- Redness of the eyes,
- Reduced sharpness of vision (poor visual acuity),
- Blurred vision, rainbows, or halos around objects,
- Sensitivity to light (photophobia),
- Dry eyes.

If you notice any of the above, you should:

- Immediately remove your lenses.
- If the discomfort or problem stops, then look closely at the lens. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, insert a new lens. After insertion of a new lens, if the problem continues, you should immediately remove the lenses and consult your study doctor.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should keep the lens off your eye and seek immediately professional identification of the problem and prompt treatment to avoid serious eye damage.

5. PERSONAL CLEANLINESS and LENS HANDLING

– **Preparing the Lens for Wearing:**

It is essential that you learn and use good hygienic methods in the care and handling of the lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.
- Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.
- Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly:
  - Less than usual comfort,
  - The lens may fold on the eye,
  - Excessive lens movement on blink,
  - Blurred vision.

If the lens folds and sticks together: Place the lens in the palm of your hand and GENTLY rub the lens between your index finger and palm in a gentle back and forth motion. Replace the lens if it does not unfold.

If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.

- **Placing the Lens on the Eye:**

There are other methods of lens placement. If the following methods are difficult for you, your study doctor will provide you with an alternate method.

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the Lens," next in these instructions).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
  - Cosmetics or oils on the lens (replace the lens),
  - The lens is on the wrong eye,

[redacted]

- The lens is inside-out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye professional.

The One-Hand Placement Technique

Place the lens on your index finger. Head up, looking straight ahead, pull down your lower eyelid with the middle finger of your placement hand. Look up steadily at a point above you. Then place the lens on the lower white part of your eye. Remove your index finger and slowly release the lower lid. Look down to position the lens properly. Close your eyes for a moment; the lens will center itself on your eye.

The Two-Hand Placement Technique

With the lens on your index finger, use the middle finger of the other hand to pull the upper lid against the brow. Use the middle finger of your placement hand to pull down the lower lid and then place the lens centrally on your eye. While holding this position, look downward to position the lens properly. Slowly release your eyelids.

If the lens feels uncomfortable, then look in the mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from your nose while looking in the opposite direction. Then by blinking, the lens will re-center itself. If the lens still feels uncomfortable, follow the steps described in the section of these instructions entitled "Adverse Reactions."

- **<u>Centering the Lens</u>**:

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens, follow one of the procedures below.

Hold the upper and lower eyelids open with your fingers. Then while looking in a mirror, gently place a finger on the contact lens and gently slide the lens towards the center of the eye.

Or

- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, move your eye towards the lens to place it on the center of the eye.

- **<u>Removing the Lens:</u>**

Always remove the same lens first.

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

[redacted]

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2) Always be sure that the lens is in the correct position on your eye before you try to remove it (a simple check of your vision, closing one eye at a time, will tell you if the lens is in the correct position). Look up and slowly pull down your lower eyelid with the middle finger of your removal hand and place your index finger on the lower edge of lens. Squeeze the lens lightly between the thumb and the index finger and remove it. Avoid sticking the edges of the lens together.

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

Note: If this method of removing your lens is difficult for you, your study doctor will provide you with an alternate method.

- **Care for a Sticking (Nonmoving) Lens:**

It is important to the health of your eyes that your contact lenses move freely. If a lens sticks (stops moving), put a few drops of the Bausch + Lomb Sensitive Eyes® Drops provided by your study doctor into your eye. In this case, do not use plain water or anything other than the recommended solutions. Do not attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of the solution or, contact your study doctor immediately. Do not attempt to remove the lens except on the advice of your study doctor.

6. EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR STUDY DOCTOR OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

APPENDIX D: FITTING GUIDE

FOR SINGLE-USE DISPOSABLE WEAR

CAUTION: Investigational device. Limited by Federal law (U.S.A.) to investigational use.

IMPORTANT

This Fitting Guide has been developed to provide professionals with information covering characteristics of the investigational daily disposable contact lens and to illustrate fitting procedures. Please read carefully and keep this information for future use. This Fitting Guide is intended for the eye care professional, but should be made available to subjects upon request. The eye care professional should provide the subject with the Subject Instructions that pertain to the subject's prescribed lens, and the recommended wearing schedule.

LENS PARAMETERS AVAILABLE (For the Test and Control lenses used in this study)

Test and Control Articles:

The Test lens to be used in this study is the Bausch + Lomb kalifilcon A daily disposable contact lens. The description of the Test lens is as follows:

- Sphere Power: -0.50 to -6.00 D in steps of 0.25 D
- Diameter: 14.2 mm
- Base Curve: 8.6 mm
- Material: kalifilcon A

A Control lens to be used in this study is the currently marketed Johnson & Johnson Acuvue Oasys® 1-Day with HydraLuxe™. The description of this Control lens is as follows:

- Sphere Power: -0.50 to -6.00 D in steps of 0.25 D
- Diameter: 14.3 mm
- Base Curve: 8.5 mm
- Material: senofilcon A

A Control lens to be used in this study is the currently marketed Alcon DAILIES TOTAL1® (delefilcon A) daily disposable contact lens. The description of this Control lens is as follows:

- Sphere Power: -0.50 to -6.00 D in steps of 0.25 D
- Diameter: 14.1 mm
- Base Curve: 8.5 mm
- Material: delefilcon A

HOW THE LENS WORKS (ACTIONS)

In their hydrated state, when the contact lens is placed on the cornea, they act as a refracting medium to focus light rays on the retina.

INDICATIONS

[redacted]

The Bausch + Lomb daily disposable contact lens is intended for the daily disposable wear correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 D or less, that does not interfere with visual acuity. The lenses may be prescribed in spherical powers ranging from -0.50 D to -6.00 D. The lenses have been prescribed for single-use disposal wear and will be replaced after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb daily disposable contact lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye,
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids,
- Severe insufficiency of lacrimal secretion (dry eyes),
- Corneal hypoesthesia (reduced corneal sensitivity),
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses,
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions,
- Any active corneal infection (bacterial, fungal, or viral),
- If eyes become red or irritated.

WARNINGS

After a thorough eye examination, including appropriate medical background, subjects should be fully apprised by the prescribing professional of all the risks with contact lens wear. Subjects should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses could result in **serious injury** to the eye. It is essential that subjects follow their eye care professional's direction and all labeling instructions for proper use of lenses. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily disposable lenses are not indicated for overnight wear, **and subjects should be instructed not to wear lenses while sleeping**. Clinical studies have shown that the risk of serious adverse reactions is increased when daily disposable lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a subject experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the subject should be instructed to **immediately remove lenses** and promptly contact his or her eye care professional.

PRECAUTIONS

Precautions for Eye Care Professionals:

- Due to the small number of subjects enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the subject's ocular health should be carefully weighed against the subject's need for refractive correction; therefore, the continuing ocular health of the subject and lens performance on eye should be carefully monitored by the prescribing eye care professional.
- Fluorescein should not be used while the subject is wearing the lenses, because the lenses will become discolored. Whenever fluorescein is used, flush the eyes with sterile saline solution. Wait at least 5 minutes before inserting new lenses. If it is not possible to flush the eyes, wait a minimum of 1 hour before inserting new lenses. If inserted too soon, the lenses may absorb residual fluorescein.
- Before leaving the eye care professional's office, the subject should be able to promptly remove lenses.
- The lenses are prescribed for disposable wear and are to be stored for return to the eye care professional once they are removed from the subject's eye. It is important that subjects be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.

Eye care professionals should carefully instruct subjects about the following safety precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the subject should be instructed to **immediately** consult his or her eye care professional. Do not attempt to remove the lens, except on the instructions of the eye care professional.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Subject Instructions and those prescribed by the eye care professional.
- Never wear lenses beyond the period recommended by the eye care professional.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care professional about wearing lenses during water activities and other sports.
- Inform the doctor (health care professional) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact the eye care professional before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the subject not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the subject's eyes. The subject should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

The subject should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain,
- Comfort is less than when lens was first placed on eye,
- Abnormal feeling of something in the eye (foreign body, scratched area),
- Excessive watering (tearing) of the eyes,
- Unusual eye secretions,
- Redness of the eyes,
- Reduced sharpness of vision (poor visual acuity),
- Blurred vision, rainbows, or halos around objects,
- Sensitivity to light (photophobia),
- Dry eyes.

If the subject notices any of the above, he or she should be instructed to:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care professional. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the subject should insert a new lens. After insertion of a new lens, if the problem continues, the subject should **immediately remove the lenses and consult the eye care professional**.

If the above symptoms continue after removal of the lens, or upon insertion of a new lens, the subject should **immediately remove the lenses and contact his or her eye care**

professional or physician, who must determine the need for examination, treatment or referral without delay.

(See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

IMPORTANT TREATMENT INFORMATION FOR ADVERSE REACTIONS

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage.

Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare and corneal infiltrates. Initial symptoms of a minor abrasion and an early-infected ulcer are sometimes similar.

Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a subject presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the subject is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

SELECTION OF SUBJECTS

Persons who require vision correction and who would not or could not adhere to the replacement regimen for the Bausch + Lomb daily disposable contact lenses or are unable to place and remove the lenses should not be provided with them. Failure to follow handling instructions could lead to serious eye infections, which might result in corneal ulcers.

Subject communication is vital because it relates not only to subject selection but also to ensure compliance. It is also necessary to discuss the information contained in the Subject Instructions with the subject at the time of the initial examination. Subjects selected to wear the Bausch + Lomb daily disposable contact lens should be chosen for their motivation to wear contact lenses, general health, and cooperation. The eye care professional must take care in selecting, examining, and instructing contact lens subjects. Subject hygiene and willingness to follow eye care professional instructions are essential to their success.

A detailed history is crucial to determining subject needs and expectations. Your subject should be questioned regarding vocation, desired lens-wearing time (full or part time), and desired lens usage (reading, recreation or hobbies). Initial evaluation of the lens should be preceded by a complete eye examination, including visual acuity, keratometry, and slit lamp examination.

It is normal for the subject to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes), and slight redness during the adaptation period.

Although the adaptation period varies for each individual, generally within one week these symptoms will disappear. If these symptoms persist, the subject should be instructed to contact his or her eye care professional.

FITTING PROCEDURE

1. Pre-fitting Examination

A pre-fitting subject history and examination are necessary to:

- determine whether a subject is a suitable candidate for daily disposable contact lenses (consider subject hygiene and mental and physical state),
- make ocular measurements for initial contact lens parameter selection, and
- collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include spherocylindrical refraction and VA, keratometry, and biomicroscopic examination.

2. Initial Lens Power Selection

- Lens power is determined from the subject's spherical equivalent prescription corrected to the corneal plane.
- Select the appropriate power lens and place the lens on the eye. Allow the lens to remain on the eye long enough (3 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.
- Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial Lens Evaluation

- To determine proper lens parameters observe the lens relationship to the eye using a slit lamp.
    - Movement: The lens should provide discernible movement with:
        - Primary gaze blink
        - Up gaze blink
        - Up gaze lag
    - Centration: The lens should provide full corneal coverage.
- Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens.

4. Criteria of a Well-Fitted Lens

If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable and provides satisfactory visual performance, it is a well-fitted lens and can be dispensed.

5. Characteristics of a Tight (Steep) Lens

A lens which is much too steep may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the subject gaze upward. A properly fitted lens will tend to slide downward approximately 0.5mm while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

6. Characteristics of a Loose (Flat) Lens

If the lens is too flat, it will:

- Decenter, especially on post-blink.
- Have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva.
- Have a tendency to be uncomfortable and irritating with fluctuating vision.
- Have a tendency to drop or lag greater than 2.0 mm on up-gaze post-blink.

7. Follow-up Care

- From the day of dispensing, the following schedule is required for this study.
    - 2-Week Follow-Up Visit
- Prior to a follow-up examination, the contact lenses should be worn for approximately 1 continuous hour and the subject should be asked to identify any problems which might be occurring related to contact lens wear.
- With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- After the lens removal, instill sodium fluorescein (unless contraindicated) into the eyes and conduct a thorough biomicroscopy examination.
    - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.
    - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
    - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens. If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions.

WEARING SCHEDULE

The wearing and daily disposable schedules should be determined by the eye care professional. Regular checkups, as determined by the eye care professional, are extremely important.

Daily Disposable:

There may be a tendency for the daily disposable subject to over-wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily disposable schedule should

be stressed to these subjects. The wearing schedule should be determined by the eye care professional. The wearing schedule chosen by the eye care professional should be provided to the subject. The lens is to be prescribed for single-use disposable wear and is to be replaced after each removal.

All subjects should be supplied with a copy of the Subject Instructions.

HANDLING OF LENSES

When lenses are dispensed, the subject should be provided with appropriate and adequate instructions and warnings for lens handling. The eye care professional should recommend appropriate and adequate procedures for each individual subject in accordance with the particular lens-wearing schedule.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving), the subject should be instructed to use their study Bausch + Lomb Sensitive Eyes® Drops. The subject should be instructed to not use plain water, or anything other than the recommended solutions. The subject should be instructed to contact the eye care professional if the lens does not begin to move upon blinking after several applications of the solution, and to not attempt to remove the lens except on the advice of the eye care professional.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in subjects wearing the Bausch + Lomb daily disposable contact lens should be reported according to the Protocol.

HOW SUPPLIED

The lenses are provided individually in a plastic blister containing sterile packaging solution. Each container is marked with the manufacturing lot number of the lens, power, base curve, and expiration date.