Johnson & Johnson Vision Care, Inc.

Clinical Study Protocol

Protocol Title: Influence of Lens Design on Particulate Exchange in the Post-lens Tear Film

Protocol CR-6291 [redacted]

Version: v1.0

Date: 06 September 2018

Investigational Products: 1-DAY ACUVUE® MOIST (base curve (BC): 8.5, 1-DAY ACUVUE® MOIST for ASTIGMATISM (BC: 8.5) and 1-DAY ACUVUE® MOIST MULTIFOCAL (BC: 8.4)

Key Words: Contact lens, post-lens tear film, particulate clearance, particulate uptake, microspheres, daily disposable, non-dispensing, etafilcon A, 1-DAY ACUVUE® MOIST, 1-DAY ACUVUE® MOIST for ASTIGMATISM, 1-DAY ACUVUE® MOIST MULTIFOCAL

Statement of Compliance to protocol, GCP and applicable regulatory guidelines:
This trial will be conducted in compliance with the protocol, ISO 14155,[1] the International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP),[2] the Declaration of Helsinki,[3] and all applicable regulatory requirements.

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PROTOCOL TITLE, NUMBER, VERSION

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SPONSOR NAME AND ADDRESS

Johnson & Johnson Vision Care (JJVC)
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Jacksonville, FL 32256

MEDICAL MONITOR

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

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

AUTHORIZED SIGNATURES

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations,[4] ICH guidelines,[2] ISO 14155,[1] and the Declaration of Helsinki.[3]

Author	Michael Read, MCOptom, PhD, Principal Investigator	12th September 2018 DATE
Study Responsible Clinician	See Electronic Signature Report Kristy Canavan OD Senior Principal Research Optometrist, JJVC	DATE
Clinical Operations Manager	See Electronic Signature Report [redacted]	DATE
Biostatistician	See Electronic Signature Report [redacted]	DATE
Reviewer	See Electronic Signature Report [redacted]	DATE
Data Management	See Electronic Signature Report [redacted]	DATE
Reviewer	See Electronic Signature Report [redacted]	DATE
Approver	See Electronic Signature Report [redacted]	DATE

CHANGE HISTORY

Version	Originator	Description of Change(s) and Section Number(s) Affected	Date
1.0	Michael Read	Original Protocol	06 September 2018

SYNOPSIS

Protocol Title	Influence of lens design on particulate exchange in the post-lens tear film
Sponsor	JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Clinical Phase	Feasibility
Trial Registration	This study will be registered on ClinicalTrials.gov.
Test Article(s)	Three contact lenses: • 1-DAY ACUVUE® MOIST (Test) • 1-DAY ACUVUE® MOIST for ASTIGMATISM (Test) • 1-DAY ACUVUE® MOIST MULTIFOCAL (Test) • Bare Eye (Control)
Wear and Replacement Schedules	Single use contact lenses worn during clinic visits only.
Objectives	The primary objective of this study is to understand the influence of contact lens design characteristics on microsphere uptake and clearance of microspheres from the post-lens tear film. The secondary objectives are (i) to investigate the influence of lens movement on microsphere uptake and clearance during contact lens wear, (ii) to investigate the influence of corneal curvature on microsphere uptake and clearance during contact lens wear and (iii) to investigate the influence of blink rate on microsphere uptake and clearance during contact lens wear.
Study Endpoints	Primary endpoint(s): • Microsphere clearance rate (C_{30} metric) • Microsphere uptake rate (U_5 metric) Secondary endpoints: • Lens movement (as assessed by clinical grading) • Corneal curvature (as assessed by Visante™ OCT) • Blink rate (as assessed by high-speed IR blink camera) Other observations: • Subjective comfort evaluation (using VAS grading scale) • Adverse events • Slit lamp findings (Efron Grading scale)

Study Design	This is a bilateral, non-dispensing, randomized, subject-masked, 4 treatment x 4 period crossover study, with microsphere clearance evaluated in the right eye and microsphere uptake evaluated in the left eye for each subject. There will be a total of five visits: Visit 1: Screening, baseline evaluation and eligibility (including lens handling assessment and Eyegenie use). Visit 2: Randomization, baseline, assessment of microsphere clearance from the post-lens tear film (right eye) and then microsphere uptake into the post-lens tear film (left eye) as per randomization table. Visits 3-5: Baseline, assessment of microsphere clearance from the post-lens tear film (right eye) and then microsphere uptake into the post-lens tear film (left eye) as per randomization table. See the flow chart at the end of the synopsis table for the schematic of the study visits and procedures of main observations (Figure 1)
Sample Size	Up to 60 subjects will be enrolled. Enrollment will cease once 25 subjects are randomized (Visit 2).
Study Duration	The study will last approximately 6 months. An enrollment period of 3 months is anticipated.
Anticipated Study Population	Habitual soft contact lens wearers, 18-40 years of age with refractive cylinder less than -1.25 DC in each eye.
Eligibility Criteria	Potential subjects must satisfy all of the inclusion criteria in section 3.2 to be enrolled in the study. Potential subjects who meet any of the exclusion criteria in section 3.3 will be excluded from participating in the study.
Disallowed Medications/Interventions	No topical ophthalmic medication (e.g. eye drops or ointments) from 24 hours prior to each visit.
Measurements and Procedures	Microsphere imaging, VAS scale comfort, lens fit and movement, Ocular Coherence Tomographer (OCT) imaging, blink rate imaging.
Microbiology or Other Laboratory Testing	None

Study Termination	The occurrence of one or more Unanticipated Adverse Device Effect (UADE), or any SAE where relationship to study agent cannot be ruled out, will result in stopping further dispensing investigational product. In the event of a UADE or SAE, the Sponsor Medical Monitor may unmask the treatment regimen of subject(s) and may discuss this with the Principal Investigator before any further subjects are enrolled.
Ancillary Supplies/ Study-Specific Materials	Sterile, preservative-free, single-use saline pods, Eyegenie, tweezers, fluorescein strips. G0100B Thermo Scientific fluorescent green 1-micron polystyrene microspheres[5] will be used in this clinical study. These microspheres will undergo disinfection by pasteurization prior to use in this study. These microspheres will then be suspended in phosphate buffered saline solution to form a 1% solids suspension (Appendix E).
Principal Investigator(s) and Study Institution(s)/Site(s)	A full list of Principal Investigators, clinical sites, and institutions is kept separately from the Study Protocol and is included in the study Trial Master File.

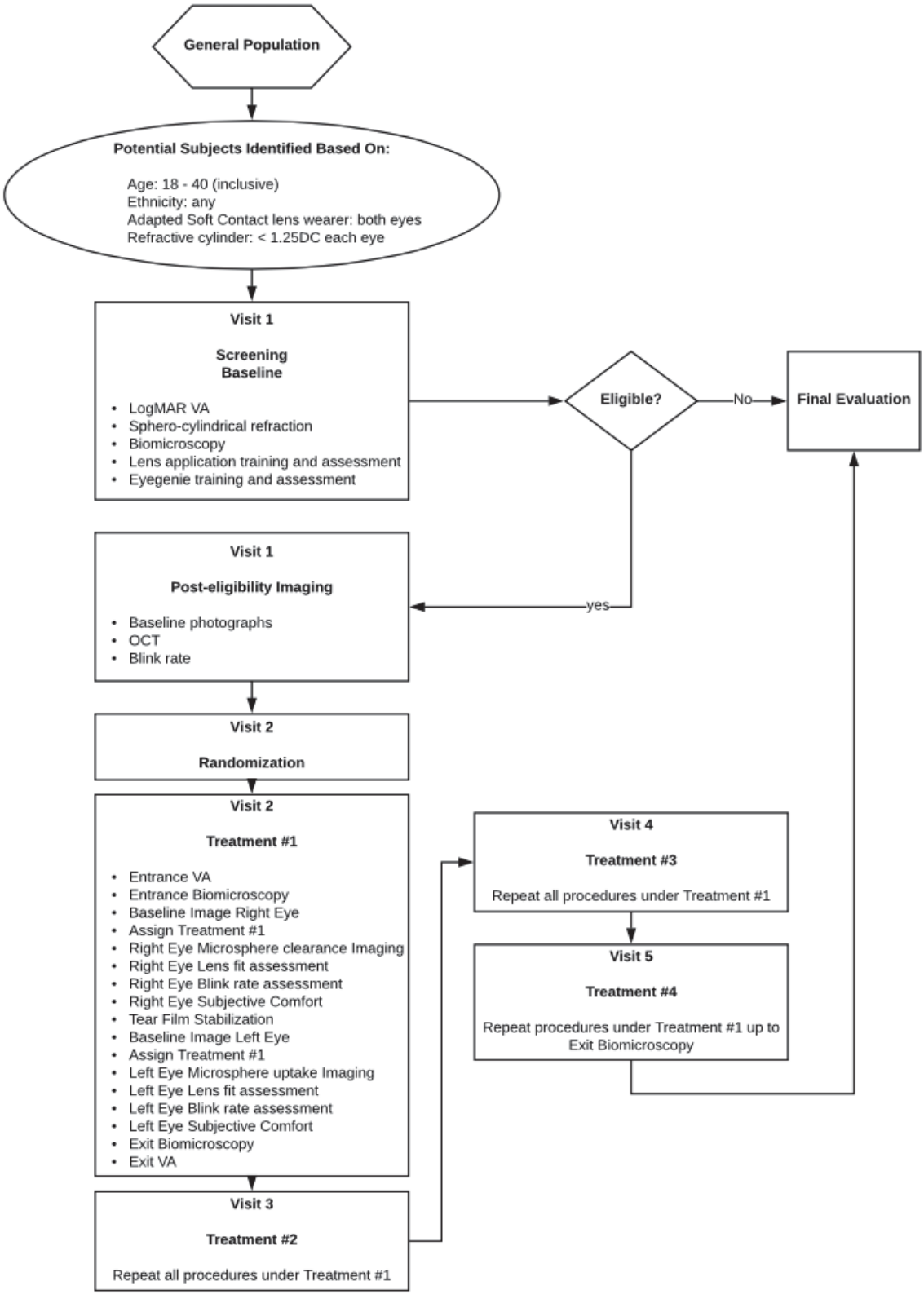

Figure 1: Study Flowchart

COMMONLY USED ABBREVIATIONS AND DEFINITIONS OF TERMS

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

PQC	Product Quality Complaint
PRO	Patient Reported Outcome
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
VA	Visual Acuity

1. INTRODUCTION AND BACKGROUND

Previous work at the University of Manchester has focused on understanding the flow of microspheres in the post-lens tear film during soft contact lens wear. These clinical studies have demonstrated that (i) microsphere particles do not influence subjective comfort or ocular surface physiology, (ii) the uptake and clearance of microspheres from the post-lens tear film appears to be a blink-driven process, (iii) contact lens wear typically slows the rate of particulate clearance from the post-lens tear film, (iv) bacterial-sized particles are able to enter the post-lens tear film during contact lens wear, (v) both microsphere uptake and microsphere clearance from the post-lens tear film appears to show a correlation with the clinical outcomes observed in previous clinical studies [redacted]

This study seeks to use our previous methodology to understand the influence of contact lens design characteristics on microsphere uptake into and clearance from the post-lens tear film.

1.1. Name and Descriptions of Investigational Products

The products used in this clinical study are three CE marked contact lenses made from the same material, etafilcon A, each having a different back surface design:

- 1-DAY ACUVUE® MOIST (Test)
- 1-DAY ACUVUE® MOIST for ASTIGMATISM (Test)
- 1-DAY ACUVUE® MOIST MULTIFOCAL (Test)
- Bare Eye (Control)

1.2. Intended Use of Investigational Products

Each contact lens design will be worn bilaterally at two of the five study visits. All lens types will be worn during Visit 1, in order to assess handling and establish eligibility. Each of the contact lens designs will then be worn bilaterally at one other study visit as dictated by the randomization table. The lenses will be worn in the clinic only, during this non-dispensing study. At Visit 1, each pair of lenses will be worn for approximately 15 minutes. At Visits 2-5 each lens will be worn for approximately 1 hour.

1.3. Summary of Findings from Nonclinical Studies

Not Applicable – Marketed products only.

1.4. Summary of Known Risks and Benefits to Human Subjects

There is no direct benefit to the subject from participation in the study. The information from this study may aid the development and design of future contact lenses.

For the most comprehensive risk and benefit information regarding the study contact lenses refer to the latest version of the package insert (Appendix C).

For the most comprehensive risk and benefit information regarding the polystyrene microspheres refer to the latest version of the IB.[5]

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

All lenses used in this study are CE marked/approved and marketed products. Please see appropriate package inserts (Appendix C: Package Insert (approved product). For relevant literature and prior clinical data relevant to the polystyrene microspheres, please refer to the latest version of the IB.[5]

2. STUDY OBJECTIVES, ENDPOINTS AND HYPOTHESES

2.1. Objectives

Primary Objective:
The primary objective is to compare the rate of microsphere uptake into, and clearance from, the post-lens tear film of three study contact lens types with different back surface designs.

Secondary Objectives:
To study the association of microsphere uptake and clearance during contact lens wear with the following factors:

1. Lens movement (assessed by clinical grading).
2. Corneal curvature (assessed using a Visante™ OCT).
3. Blink rate (assessed using a high-speed infrared camera).

Other observations:

- Subjective comfort evaluation (using VAS grading scale)
- Adverse events
- Slit lamp findings (Efron Grading scale)

2.2. Endpoints

Primary Endpoint(s)

The primary endpoints in this study are (i) the rate of microsphere clearance from the post-lens tear film, as assessed by the C_{30} image analysis metric and (ii) the rate of microsphere uptake into the post-lens tear film, as assessed by the U_5 image analysis metric.

The C_{30} metric was developed in a previous clinical study [redacted] to quantify the rate of microsphere clearance from the post-lens tear film following microsphere application on the concave lens surface prior to lens application.

The U_5 metric was developed in the previous clinical study [redacted] to quantify the rate of microsphere uptake into the post-lens tear film following microsphere application onto the conjunctival surface during lens wear.

Secondary Endpoint(s)

The secondary endpoints in this study are lens movement (as assessed by a clinical grading scale), corneal curvature (as assessed using a Visante™ OCT) and blink rate (as assessed using a high-speed infrared camera).

2.3. Hypotheses

Primary Hypotheses:

- The rate of microsphere clearance from the post-lens tear film (as assessed by the image analysis metric C_{30}) is equivalent between the study lens types. An equivalence margin of 10% will be used.
- The rate of microsphere uptake into the post-lens tear film (as assessed by the image analysis metric U_5) is equivalent between the study lens types. An equivalence margin of 10% will be used.

3. TARGETED STUDY POPULATION

3.1. General Characteristics

The study population will be healthy adapted soft contact lens wearers between 18-40 years of age from a single site in the UK.

3.2. Inclusion Criteria

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

Inclusion Criteria after Screening

1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form.
2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. The subject must be between 18 and 40 (inclusive) years of age at the time of screening.
4. The subject must own a wearable pair of spectacles and be willing to wear them to each study visit.
5. The subject must be an adapted soft contact lens wearer in both eyes, having successfully worn contact lenses in the last six months by self-report.
6. The subject must agree not to participate in other clinical research for the duration of this study.

Inclusion Criteria after Baseline

7. The subject's refractive cylinder must be <-1.25DC in each eye.
8. The subject must have best corrected visual acuity of *0.20 logMAR* or better in each eye.

3.3. Exclusion Criteria

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

Exclusion Criteria after Screening:

1. Currently pregnant or breast feeding (self-reported).
2. Any systemic disease (e.g., Sjögren's Syndrome), infectious disease (e.g., hepatitis, tuberculosis), contagious immunosuppressive diseases (e.g., HIV), autoimmune disease (e.g. rheumatoid arthritis), or other diseases, by self-report, which are known to interfere with contact lens wear and/or participation in the study (at the Investigator's discretion).
3. Use of topical medication such as eye drops or ointment within 24 hours prior to the study visit.
4. Any history of anaphylaxis or severe allergy.
5. Any previous, or planned (during the course of the study) ocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.)
6. Participation in any contact lens or lens care product clinical trial within 14 days prior to study enrollment
7. Employee or immediate family member of an employee of clinical site (e.g., Investigator, Coordinator, Technician)

Exclusion Criteria after Baseline

8. They have any slit lamp findings of grade 3 or higher (e.g. corneal oedema, corneal neovascularization, tarsal abnormalities, conjunctival injection) or findings of < Grade 3 which in the investigator's opinion would contraindicate contact lens wear.

3.4. Enrollment Strategy

Study subjects will be recruited from the Eurolens Research (The University of Manchester) subject database and/or utilizing Independent Ethics Committee (IEC) or Institutional Review Board (IRB) approved materials.

4. STUDY DESIGN AND RATIONALE

4.1. Description of Study Design

This is a 5-visit, controlled, bilateral, randomized, subject-masked, crossover (4 treatments x 4 period), non-dispensing study.

Subjects will attend all study visits in their spectacle correction having not worn contact lenses on the day of the Visit.

At Visit 1, subjects will be consented and screened for the inclusion/exclusion criteria. An assessment of the subject's ability to (i) apply the three study lens types to their right eye (facing downwards during lens application – see Appendix H) and (ii) hold both eyelids with

the EyeGenie device during image capture will be completed. If a subject is found to meet all the eligibility criteria and to have optimal lens application and Eyegenie technique, baseline photographs (Appendix I) will be captured during wear of each of the study lens types. In addition, corneal curvature (assessed using the Visante™ OCT) and blink rate (assessed using a high-speed infrared camera) (Appendix J) will be evaluated without study lenses in place.

At Visit 2 subjects will be randomized and at Visits 2-5 microsphere uptake and clearance from the post-lens tear film will be assessed for the assigned study treatment as follows:

Right Eye

The right eye will always be assessed first and will be used to evaluate microsphere clearance. Where bare eye is assigned, a droplet of microsphere suspension will be applied directly onto the superior temporal conjunctiva (Appendix E). Where lens wear is assigned, the microsphere suspension will be dispensed onto the posterior concave contact lens surface immediately prior to lens application (Appendix E). A series of digital images will be taken over a 30-minute period (every minute for the first 10 minutes and then every 5 minutes for the next 20 minutes). Post-visit image analysis will enable calculation of the C_{30} image analysis metric.

Lens fit (Appendix D), blink rate during lens wear (Appendix J), if applicable, and subjective comfort (Appendix A) will be assessed at the 30-minute time point prior to lens removal (if applicable) and saline rinse.

A 15-minute washout period will follow to allow the tear film to settle, prior to imaging the left eye.

Left Eye

The left eye will be used to evaluate microsphere uptake. Where bare eye is assigned, a droplet of microsphere suspension will be applied directly onto the superior temporal conjunctiva (Appendix E). Where a lens is assigned the lens will be applied and after a 10-minute settling period, a droplet of microsphere suspension will be applied directly to the superior temporal conjunctiva (Appendix E). A series of digital images will be taken over a 10-minute period (every minute for 10 minutes). Post Visit image analysis will enable calculation of the U_5 image analysis metric. Lens fit (Appendix D), blink rate during lens wear (Appendix J), if applicable, and subjective comfort (Appendix A) will be assessed at the 10-minute time point prior to lens removal (if applicable) and saline rinse.

The identity of the study lenses will be masked to the subject. The subject will not be able to see the identity of the study lenses since the Investigator will be preparing the lenses out of sight of the subject. If any of the lens applications are unsuccessful the eye will be rinsed with sterile saline and the subject left for at least 15 minutes for their tear film to restabilize and any remaining microspheres to clear from the ocular surface. Successful rinsing of the microspheres will be confirmed by slit lamp examination, prior to the subject reattempting lens application, with additional time given if microspheres are still observable.

No more than one study visit can occur on any given day (consecutive days are allowed). The subjects will be asked to attend for all study visits in their spectacle correction (or without correction if not required), having not worn contact lenses on that day.

4.2. Study Design Rationale

Crossover designs are a well-established cost-effective study design in which subjects are exposed to multiple treatments during different time periods. This design was considered because patient-specific factors that might affect microsphere uptake and clearance are well controlled. A thorough rinse of each eye after microsphere evaluations, no more than one study visit per day, and a washout period of at least 24 hours reduce any potential carry-over effect that may bias the results.

4.3. Enrollment Target and Study Duration

A total of up to 60 subjects will be enrolled (informed consent signed) at a single clinical site (Eurolens Research at The University of Manchester) in the UK. Enrollment will end once 25 subjects have been randomized. The goal is a sample size of approximately 20 subjects.

The study will last approximately 6 months and include a 3-month enrollment period.

Once the informed consent has been signed the subject will be considered enrolled.

5. TEST ARTICLE ALLOCATION AND MASKING

5.1. Test Article Allocation

At Visit 1, eligible subjects will be asked to apply and then remove a pair of each of the three study lens types, to allow an assessment of lens handling technique. If lens application and Eyegenie use is optimal they will apply a further pair of each of the three study lens types, to allow baseline images to be captured.

At Visits 2-5, a bilateral crossover design will be used, where at each of the four study visits, a test lens (or the bare eye condition) will be allocated to both of the subject's eyes, according to the randomization scheme (both eyes randomized together). The randomization will be such that on completion of these four study Visits (Visits 2-5), each subject will have worn all three lens types and been assigned the bare eye condition in both eyes. In order to allow sufficient time for a series of anterior segment photographs to be captured, lens application will be staggered, such that the left lens will be applied only after completion of imaging and lens removal in the right eye.

The study lenses will be worn in a bilateral and random fashion using a Williams design with 4 treatments and 4 wear periods. Each subject will be randomly assigned to one of four unique sequences (Test1/Test2/Control/Test3, Test2/Test3/Test1/Control, Test3/Control/Test2/Test1, Control/Test1/Test3/Test2).

Use of the test articles will be randomized using a randomization scheme supplied by the study biostatistician. The clinical site will follow the randomization scheme provided and will

complete enrollment according to the randomization list and will not pre-select or assign subjects.

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

5.2. Masking

Subjects will be unaware of the identity of the investigational product, since the investigator will be preparing the lenses out of sight of the subject. Investigators and clinical site personnel involved in the data collection will not be masked as to the identity of the investigational product, with the exception of the person responsible for performing the image analysis (these videos will be coded prior to analysis to avoid any potential bias).

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

Subjects who have had their treatment assignment unmasked are expected to return for all remaining scheduled evaluations. Subjects who are discontinued will not be replaced.

5.3. Procedures for Maintaining and Breaking the Masking

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

When dispensing (placed/fit on eye) test articles, the following steps should be followed to maintain randomization codes:

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

6. STUDY INTERVENTION

6.1. Identity of Test Articles

The following contact lenses will be used in this study:

Table 1: Test Articles

	Test 1	Test 2	Test 3	Control
Name	1-DAY ACUVUE® MOIST	1-DAY ACUVUE® MOIST for ASTIGMATISM	1-DAY ACUVUE® MOIST MULTIFOCAL	Bare Eye
Manufacturer	Johnson & Johnson Vision Care, Inc.	Johnson & Johnson Vision Care, Inc.	Johnson & Johnson Vision Care, Inc.	N/A
Lens Material	etafilcon A	etafilcon A	etafilcon A	N/A
Nominal Base Curve @ 22 ºC	8.5	8.5	8.4	N/A
Nominal Diameter @ 22 ºC	14.2	14.5	14.3	N/A
Nominal Distance Powers (D)	-0.50	-0.50	-0.50	N/A
Nominal Cylinder Powers (D) and Axes	N/A	-0.75 x180	N/A	N/A
Nominal ADD Powers (D)	N/A	N/A	LOW	N/A
Oxygen Permeability (Dk) (FATT/ISO)	28/21	28/21	28/21	N/A
Design	spherical	toric	multifocal	
Wear Schedule in Current Study	Non-dispensing	Non-dispensing	Non-dispensing	N/A
Replacement Frequency	single use	single use	single use	N/A
Packaging Form (vial, blister, etc.)	blister	blister	blister	N/A

It is estimated that if up to 60 subjects use up to 6 of each lens type during Visit 1 (3 x 6 x 60 subjects = 1080 lenses) and 25 are subsequently randomized and use up to 4 of each lens types during Visits 2-5 (3 x 4 x 25 = 300) a total of approximately 1380 lenses (460 of each lens type) will be required.

6.2. Ancillary Supplies/Products

The following solutions will be used in this study:

Table 2: Ancillary Supplies

	Solution			
Solution Name/Description	Saline pods	Phosphate buffered saline solution	G0100B fluorescent green 1-micron polystyrene microspheres	Fluorescein Strips
Manufacturer	Any sponsor-approved manufacturer of sterile, preservative free, single use eye wash (0.9% w/v sodium chloride solution)	CooperVision (or alternative Sponsor-approved product)	Thermo Scientific	Contacare Ophthalmics and Diagnostics (or alternative Sponsor-approved product)
Preservative	None	None	None	None
Other distinguishing items (dye, packaging, approval status, etc.	CE marked	CE marked	See Investigator Brochure	100 strips, CE marked

6.3. Administration of Test Articles

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

6.4. Packaging and Labeling

The test articles will be packaged in blisters as the primary packaging. The test articles will be in commercial cartons as the secondary packaging form. The sample study label is shown below:

6.5. Storage Conditions

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

6.6. Collection and Storage of Samples

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

6.7. Accountability of Test Articles

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

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

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

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

7. STUDY EVALUATIONS

7.1. Time and Event Schedule

Table 3: Time and Events

Visit Information	Visit 1 Screening, Baseline,	Visit 2 Treatment 1	Visit 3 Treatment 2	Visit 4 Treatment 3	Visit 5 Treatment 4, Final Evaluation
Time Point		≥24 hours to 28 days after V1	≥24 hours to 28 days after V2	≥24 hours to 28 days after V3	≥24 hours to 28 days after V4
Estimated Visit Duration	2.5 hours	2 hours	2 hours	2 hours	2 hours
Statement of Informed Consent/Privacy statement	X				
Demographics	X				
Medical History/Concomitant Medications	X	X	X	x	x
Habitual Contact Lens Information	X				
Inclusion/Exclusion Criteria (Screening)	X				
Entrance LogMAR Visual Acuity	X	X	X	x	x
Subjective Sphero-Cylindrical Refraction	X				
Entrance Slit Lamp Biomicroscopy (no fluorescein used at V2-5)	X	x	X	x	x
Inclusion/Exclusion Criteria (Baseline)	X				
Lens Application training and assessment	X				
Eyegenie training and assessment	X				
Baseline Lens Wear Imaging	X				
OCT Anterior Segment Imaging	X				
Blink Rate Imaging	X	x	X	x	x
Exit Slit Lamp Biomicroscopy	X	x	X	x	x
Exit LogMAR Visual Acuity	X	x	x	x	x
Adverse Events and Concomitant Medications Review		x	x	x	x
Randomization		x			
Right Eye Baseline Imaging (prior to microsphere application)		x	x	x	x
Right Eye Assign Study Treatment		x	x	x	x
Right Eye Lens and/or Microsphere preparation/application		x	x	x	x
Right Eye Microsphere Clearance Imaging		x	x	x	x
Right Eye Lens Fit Assessment		x	x	x	x
Right Eye Subjective Comfort		x	x	x	x
Right Eye Lens Removal (if applicable) and saline rinse		x	x	x	x
Tear Film Stabilization		x	x	x	x
Left Eye Baseline Imaging (prior to microsphere application)		x	x	x	x
Left Eye Assign Study Treatment		x	x	x	x
Left Eye Lens and/or Microsphere preparation/application		x	x	x	x
Left Eye Microsphere Uptake Imaging		x	x	x	x
Left Eye Lens Fit Assessment		x	x	x	x
Left Eye Subjective Comfort		x	x	x	x
Left Eye Lens Removal (if applicable) and saline rinse		x	x	x	x

Final Evaluation					x

7.2. Detailed Study Procedures

VISIT 1

The subjects must present to Visit 1 wearing spectacles, not having worn contact lenses on the day of the visit.

Visit 1: Screening			
Step	Procedure	Details	[redacted]
1.1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the consent form. **Note**: The subject must be provided with a signed copy of this document.	
1.2	Demographics	Record the subject's date of birth, gender, race and ethnicity.	
1.3	Medical History and Concomitant Medications	Questions regarding the subject's medical history and concomitant medications.	
1.4	Habitual Lenses	Questions regarding the subject's habitual lens type and parameters.	
1.5	Eligibility after Screening	All responses to Screening Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria must be answered "no" for the subject to be considered eligible. *If subject is deemed to be ineligible after screening, proceed to Final Evaluation and complete Subject Disposition. Refraction and Biomicroscopy forms are not required.*	

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.6	Entrance Visual Acuity	Record distance high contrast LogMAR visual acuity (OD and OS) with their habitual spectacle correction in place.	Eurolens Research SOP # 12a (Appendix F)

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.7	Subjective Sphero-cylindrical Refraction	Complete subjective sphero-cylindrical refraction and record the resultant distance LogMAR visual acuity (OD and OS)	Eurolens Research SOP # 12a (Appendix F)
1.8	Slit Lamp Biomicroscopy	The Efron Slit Lamp Classification Scale will be used to grade the findings and determine eligibility (excluding assessment with sodium fluorescein). If any of these slit lamp findings are grade 3 or higher or findings of < grade 3 which in the investigator's opinion would contraindicate contact lens wear, the subject may not continue at this time, but may return up to one additional time to determine eligibility. If discontinued a final examination must be completed. PLEASE NOTE: This will NOT include assessment with sodium fluorescein as this adversely influences baseline imaging.	Eurolens Research SOP # 13 (Appendix G)
1.9	Eligibility after Baseline	All responses to Inclusion Criteria questions must be answered "yes" and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible. If subject is deemed to be ineligible after baseline, proceed to Final Evaluation and complete all forms.	
1.10	Lens application training and assessment	Instruction on how to apply lenses in the study specific manner followed by practice and further guidance where needed. Assessment of the subject's ability to successfully apply each lens type (OD only). If subject is deemed to have non-optimal lens application technique proceed to Final Evaluation and complete all forms.	Work Aid: Criteria for assessment of optimal/non-optimal lens application and Eyegenie technique. (Appendix H)

Visit 1: Baseline			
Step	Procedure	Details	[redacted]
1.11	Eyegenie	Instruction on how to use the Eyegenie followed by practice and further guidance where needed. Assessment of the subjects Eyegenie use (OD and OS). If subject is deemed to have non-optimal Eyegenie technique proceed to Final Evaluation and complete all forms.	Work Aid: Criteria for assessment of optimal/non-optimal lens application and Eyegenie technique. (Appendix H)

Visit 1: Post-eligibility Supplementary Imaging			
Step	Procedure	Details	[redacted]
1.12	Baseline photographs	Baseline images of the subject wearing each lens type (OD and OS).	Work Aid: APPENDIX I: Image capture system and procedures
1.13	Anterior segment imaging	Anterior segment (OD and OS) will be imaged using the Visante™ OCT. Corneal angle will be calculated as detailed by Ritzmann 2017.[11]	
1.14	Baseline blink rate imaging	Blink rate will be assessed with a high-speed infra-red camera (without contact lenses)	Work Aid: APPENDIX J: Blink analysis
1.15	Exit biomicroscopy	The Efron Slit Lamp Classification Scale will be used to grade the findings. Adverse events shall be documented and followed for significant slit lamp findings.	Eurolens Research SOP # 13 (Appendix G)
1.16	Exit Visual Acuity	Record distance high contrast LogMAR visual acuity (OD and OS) with their habitual spectacle correction in place.	Eurolens Research SOP # 12a (Appendix F)
1.17	Instructions	Eligible subjects will be reminded to attend visit 2 wearing their habitual spectacles, having not worn contact lenses on the day of the visit.	

VISIT 2-5

The subjects must present to Visits 2-5 wearing spectacles, not having worn contact lenses on the day of the visit.

Visits 2-5: Treatments 1-4			
Step	Procedure	Details	[redacted]
2.1.	Randomization (at visit 2 only)	The subject will be assigned a line on the randomization scheme.	
2.2.	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
2.3.	Entrance Visual Acuity	Record distance high contrast LogMAR visual acuity (OD and OS,) with their habitual spectacle correction in place.	Eurolens Research SOP # 12a (Appendix F)
2.4.	Slit Lamp Biomicroscopy	The Efron Slit Lamp Classification Scale will be used to grade the findings (excluding assessment with sodium fluorescein). Adverse events shall be documented and followed for significant slit lamp findings. PLEASE NOTE: This will NOT include assessment with sodium fluorescein as this adversely influences baseline imaging.	Eurolens Research SOP # 13 (Appendix G)
2.5.	Continuance	Determine whether the subject is eligible to continue in the study based on the examination findings.	
2.6.	Right Eye Baseline imaging	Prior to microsphere application, a baseline image will be taken with the subject using the Eyegenie (OD).	Work Aid: APPENDIX I: Image capture system and procedures
2.7.	Right Eye Assign study treatment	Assign the study treatment, based on the randomization scheme. Record lens details if applicable.	
2.8.	Right eye Lens and/or Microsphere preparation/application	If bare eye is assigned, a droplet of microsphere suspension will be applied directly onto the superior temporal conjunctiva. If lens wear is assigned the microsphere suspension will be dispensed onto the posterior concave contact lens	Work Aid: Methodology for ocular instillation of fluorescent microspheres

Visits 2-5: Treatments 1-4			
Step	Procedure	Details	[redacted]
		surface immediately prior to lens application.	(Appendix E)
2.9.	Right Eye Microsphere clearance imaging	Images will be captured immediately after microsphere application, every minute for 10 minutes and then every 5 minutes for the next 20 minutes. The subject will use the Eyegenie to allow the entire contact lens, where applicable, to be imaged.	Work Aid: APPENDIX I: Image capture system and procedures
2.10.	Right Eye Lens fit (if applicable)	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement • edge lift • excessive movement in primary and up gaze • insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up	CTP-2008 (Appendix D)
2.11.	Right eye Blink rate imaging	Blink rate will be assessed with a high-speed infra-red camera.	Work Aid: APPENDIX J: Blink analysis
2.12.	Right Eye Subjective comfort	The subject will complete the VAS comfort questionnaire	CTP-2032 (Appendix A) & VAS Scale (Appendix K)
2.13.	Right Eye Lens removal (if applicable) and saline rinse	The right eye will be rinsed with sterile saline (following lens removal if applicable).	
2.14.	Tear Film stabilization	At least a 15-minute washout period to allow the tear film to settle before imaging the left eye.	
2.15.	Left Eye Baseline imaging	Prior to microsphere application, a baseline image will be taken with the subject using the Eyegenie (OS).	Work Aid: APPENDIX I: Image

Visits 2-5: Treatments 1-4			
Step	Procedure	Details	[redacted]
			capture system and procedures
2.16.	Left Eye Assign study treatment	Assign the study treatment, based on the randomization scheme. Record lens details if applicable.	
2.17.	Left Eye Lens and/or Microsphere preparation/application	If a lens is assigned it should be applied and left to settle for 10 minutes prior to microsphere application. A droplet of microsphere suspension will be applied directly onto the superior temporal conjunctiva.	Work Aid: Methodology for ocular instillation of fluorescent microspheres (Appendix E)
2.18.	Left Eye Microsphere uptake imaging	Images will be captured immediately after microsphere application and every minute for 10 minutes. The subject will use the Eyegenie to allow the entire contact lens, where applicable, to be imaged.	Work Aid: APPENDIX I: Image capture system and procedures
2.19.	Left Eye Lens fit (if applicable)	Evaluate overall lens fit acceptance (acceptable or unacceptable) based on centration, movement and other fitting characteristics. An unacceptable fit is deemed by one of the following criteria: • limbal exposure at primary gaze or with extreme eye movement • edge lift • excessive movement in primary and up gaze insufficient movement in all three of the following conditions: primary gaze, up gaze, and Josephson push up	CTP-2008 (Appendix D)
2.20.	Left eye Blink rate imaging	Blink rate will be assessed with a high-speed infra-red camera.	Work Aid: APPENDIX J: Blink analysis
2.21.	Left Eye Subjective comfort	The subject will complete the VAS comfort questionnaire	CTP-2032 (Appendix A)

Visits 2-5: Treatments 1-4			
Step	Procedure	Details	[redacted]
2.22.	Left Eye Lens removal (if applicable) and saline rinse	The left eye will be rinsed with sterile saline (following lens removal if applicable). If visit 5, proceed to Final Evaluation.	
2.23.	Exit biomicroscopy (Visits 2-4 only)	The Efron Slit Lamp Classification Scale will be used to grade the findings (including assessment with sodium fluorescein). Adverse events shall be documented and followed for significant slit lamp findings.	Eurolens Research SOP # 13 (Appendix G)
2.24.	Exit Visual Acuity (Visits 2-4 only)	Record distance high contrast LogMAR visual acuity (OD and OS) with their habitual spectacle correction in place.	Eurolens Research SOP # 12a (Appendix F)
2.25.	Instructions (Visits 2-4 only)	Subjects will be reminded to attend visit wearing their habitual spectacles, having not worn contact lenses on the day of the visit.	

FINAL EVALUATION

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

Final Evaluation			
Step	Procedure	Details	[redacted]
F.1	Final Exam Form	Indicate if the subject completed the study successfully. If subject discontinued from the study, indicate the reason.	
F.2	Exit Slit Lamp Biomicroscopy	The Efron Slit Lamp Classification Scale will be used to grade the findings (including assessment with fluorescein). Adverse events shall be documented and followed for significant slit lamp findings.	Eurolens Research SOP # 13 (Appendix G)
F.3	Exit Visual Acuity	Record distance high contrast LogMAR visual acuity (OD and OS) with their habitual spectacle correction in place.	Eurolens Research SOP # 12a (Appendix F)

7.3. Unscheduled Visits

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

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

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

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

The following information will be collected during an unscheduled visit.

Unscheduled Visit			
Step	Procedure	Details	[redacted]
U.1	Chief Complaints	Record the subject's chief complaints for reasons for the unscheduled visit.	
U.2	Adverse Events and Concomitant Medications Review	Review any changes to the subject's medical history or concomitant medications from the previous study visit. Record any changes, and any adverse events.	
U.3	Entrance Visual Acuity	Record distance high contrast LogMAR visual acuity (OD and OS) with their habitual spectacle correction in place.	Eurolens Research SOP # 12a (Appendix F)
U.4	Subjective Sphero-cylindrical Refraction	Complete subjective sphero-cylindrical refraction and record the resultant distance LogMAR visual acuity (OD and OS)	Eurolens Research SOP # 12a (Appendix F)
U.5	Slit Lamp Biomicroscopy	The Efron Slit Lamp Classification Scale will be used to grade the findings.	Eurolens Research SOP # 13

Unscheduled Visit			
Step	Procedure	Details	[redacted]
		(All ocular AE's must be followed to resolution).	(Appendix G)
U.6	Exit Visual Acuity	Record distance high contrast LogMAR visual acuity (OD and OS) with their habitual spectacle correction in place.	Eurolens Research SOP # 12a (Appendix F)

7.4. Laboratory Procedures

Not applicable.

8. SUBJECTS COMPLETION/WITHDRAWAL

8.1. Completion Criteria

Subjects are considered to have completed the study if they:

- Provided informed consent
- They are eligible
- Have completed all study visits
- Have not withdrawn/discontinued from the study for any reason described in Section 8.2

8.2. Withdrawal/Discontinuation from the Study

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

- Subject death during the study period
- Subject withdrawal of consent
- Subject not compliant to protocol
- Subject lost to follow-up
- Subject no longer meets eligibility criteria (e.g. the subject becomes pregnant)
- Subject develops significant or serious adverse events causing discontinuation of study lens wear
- Subjects who have experienced a Corneal Infiltrative Event (CIE)
- Investigator's clinical judgment regarding the subject safety reasons (that it is in the best interest of the subject to stop treatment)
- Subject demonstrates poor lens application and/or non-optimal Eyegenie technique, during visits 2-5, leading to missing microsphere clearance or uptake data on two occasions (i.e. no imaging was possible on two occasions).

For discontinued subjects, the Investigator will:

- Complete the current visit (scheduled or unscheduled)
- Complete the Final Evaluation, indicating the reason that the subject was discontinued from the study

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

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

9. PRE-STUDY AND CONCOMITANT INTERVENTION/MEDICATION

Concomitant medications will be documented during screening and updated during the study. Disallowed medications for this study include: Use of topical medication such as eye drops or ointment within 24 hours prior to the study visit.

10. DEVIATIONS FROM THE PROTOCOL

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

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

11. STUDY TERMINATION

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

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

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

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

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

12. PROCEDURE FOR HANDLING PRODUCT QUALITY COMPLAINTS

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

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

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

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

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

- Date the complaint was received/recorded in the EDC System (Date of Sponsor Awareness)
- Who received the complaint
- Study number
- Clinical site information (contact name, site ID, telephone number)
- Lot number(s)
- Unique Subject Identifier(s)
- Indication of who first observed complaint (site personnel or subject)
- OD/OS indication, along with whether the lens was inserted
- Any related AE number if applicable
- Detailed complaint description (scheduled/unscheduled visit, wear time, symptoms, resolution of symptoms, etc.)

- Eye Care Provider objective (slit lamp) findings if applicable
- Confirmation of product availability for return (and tracking information, if available), or rationale if product is not available for return [redacted] for test article return instructions)

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

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

13. ADVERSE EVENTS

13.1. Definitions and Classifications

Adverse Event (AE) – An AE is "any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device.
Note 1 to entry: This definition includes events related to the investigational medical device or the comparator.
Note 2 to entry: This definition includes events related to the procedures involved.
Note 3 to entry: For users or other persons, this definition is restricted to events related to investigational medical devices."[1]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13.2. Assessing Adverse Events

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

- Seriousness/Classifications (see definition in Section 13.1)
- Causality or Relatedness – i.e. the relationship between the test article, study treatment or study procedures and the adverse event (not related; unlikely related; possibly related; related - see definition in Section 13.2.1)
- Adverse Event Severity – Adverse event severity is used to assess the degree of intensity of the adverse event (mild; moderate; severe for all events - see definition in Section 13.2.2)
- Outcome – not recovered or not resolved; recovering or resolving; recovered or resolved with sequelae; recovered or resolved; death related to adverse event; unknown
- Actions Taken – none; temporarily discontinued; permanently discontinued; other

13.2.1. Causality Assessment

Causality Assessment – A determination of the relationship between an adverse event and the test article. The test article relationship for each adverse event should be determined by the investigator using these explanations:

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

13.2.2. Severity Assessment

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

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

13.3. Documentation and Follow-Up of Adverse Events

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

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

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

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

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

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

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

Subjects who present with an adverse event shall be followed by the Investigator, within licensure, until all signs and symptoms have returned to pre-treatment status, stabilized, or been satisfactorily resolved. If further treatment beyond licensure is required, the patient will be referred to the appropriate health care provider. The Investigator will use his/her clinical judgment as to whether a subject reporting with an adverse event will continue in the study. If a subject is discontinued from the study, it will be the responsibility of the Investigator to record the reason for discontinuation. The Investigator will also document the adverse event appropriately and complete the Adverse Event eCRF. Any subjects with ongoing adverse events related to the test article, study treatment or study procedures, as of the final study visit date, should be followed to resolution of the adverse event or until referral to an appropriate health care provider, as recommended by the Investigator. Non-ocular adverse events that are not related to the test article, study treatment, or study procedures may be recorded as "ongoing" without further follow-up.

13.4. Reporting Adverse Events

The Investigator will notify the Sponsor of an adverse event by e-mail, facsimile, or telephone as soon as possible and no later than 24 hours from discovery for any serious /significant

adverse events, and 2 days from discovery for any non-significant adverse event. In addition, a written report will be submitted by the Principal Investigator to the IEC/IRB according to their requirements (Section 13.4.2). The report will comment whether the adverse event was considered to be related to the test article, study treatment or study procedures.

13.4.1. Reporting Adverse Events to Sponsor

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

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

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

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

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

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

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

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

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

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

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

13.4.3. Event of Special Interest

None

13.5. Reporting of Pregnancy

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

14. STATISTICAL METHODS

14.1. General Considerations

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

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

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

This is a feasibility study and further exploratory analysis can be undertaken if necessary at the discretion of the study responsible clinician.

14.2. Sample Size Justification

This work is a feasibility study and a full power analysis will not be done. Previous work and clinical experience suggests that assessment of up to 60 subjects, in Visit 1, will provide at

least 25 subjects with optimum lens application technique. In visits 2-5 of this study, clinical experience indicates that 20 subjects will provide reasonable data to allow for formulation of future hypotheses. To take into account the potential for subject dropouts, the plan is to enroll 25 subjects into visit 2 of this study.

The table below, provided using the POWER procedure in SAS 9.4, summarizes statistical power based on the following assumptions:

- Testing for an equivalence margin of 10% in microsphere uptake/clearance
- True difference in microsphere uptake/clearance between study lenses of -5, 0, and 5%
- Estimated standard deviations of 5 and 10%
- Intraclass correlations of 0.4, 0.6, and 0.8
- Two-sided type I error rate of 0.05
- 20 subjects successfully complete the study

Table 4: Power Analysis for the Primary Hypotheses (Equivalence)

		Intraclass Correlation		
Difference	Estimated Standard Deviation	0.4	0.6	0.8
-5.0%	5%	0.989	>.999	>.999
-5.0%	10%	0.627	0.778	0.961
0.0%	5%	>.999	>.999	>.999
0.0%	10%	0.978	0.998	>.999
5.0%	5%	0.989	>.999	>.999
5.0%	10%	0.627	0.778	0.961

The study appears to be appropriately powered (power above 80%) for the majority of assumptions described above.

14.3. Analysis Populations

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

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

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

14.4. Level of Statistical Significance

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

14.5. Primary Analysis of Microsphere Uptake and Clearance by Lens Type

Microsphere Uptake

Microsphere uptake (left eye) will be analyzed using a (generalized) linear mixed model depending on the distribution of the response, adjusting for baseline values as a fixed covariate. The model will include the following experimental design factors: lens type, sequence of lens wear, period, and first-order carryover effect as fixed effects; subject/eye as a random effect. Baseline characteristics such as age and gender may be included as covariates when appropriate. The covariance between residual errors for the same eye across periods will be modeled using one of the following covariance structures: Compound Symmetry (CS) or Unstructured (UN). The covariance structure that returns the lowest Akaike Information Criteria Corrected (AICC) will be selected as the structure that best fits the data. The Kenward and Roger method[10] will be used for the calculation of denominator degrees of freedom.

The null and alternative hypothesis for equivalence of microsphere uptake between study lens types, where $\mu_1 - \mu_2$ is the difference in microsphere uptake between any two study lens types, is as follows:

$$H_0: |\mu_1 - \mu_2| \geq 10\%$$
$$H_0: |\mu_1 - \mu_2| < 10\%$$

The hypothesis will be tested via corresponding two-sided 95% confidence interval for least-squares mean difference (between any two study lens types) in microsphere uptake. Equivalence will be concluded if the upper limit is less than 10% and the lower limit is greater than -10%.

Microsphere Clearance

Microsphere clearance (right eye) will be analyzed using a (generalized) linear mixed model depending on the distribution of the response, adjusting for baseline values as a fixed covariate. The model will include the following experimental design factors: lens type, sequence of lens wear, period, and first-order carryover effect as fixed effects; subject/eye as a random effect. Baseline characteristics such as age and gender may be included as covariates when appropriate. The covariance between residual errors for the same eye across periods will be modeled using one of the following covariance structures: Compound Symmetry (CS) or Unstructured (UN). The covariance structure that returns the lowest Akaike Information Criteria Corrected (AICC) will be selected as the structure that best fits the data. The Kenward and Roger method[10] will be used for the calculation of denominator degrees of freedom.

The null and alternative hypothesis for equivalence of microsphere clearance between study lens types, where $\mu_1 - \mu_2$ is the difference in microsphere clearance between any two study lens types, is as follows:

$$H_0: |\mu_1 - \mu_2| \geq 10\%$$
$$H_0: |\mu_1 - \mu_2| < 10\%$$

The hypothesis will be tested via corresponding two-sided 95% confidence interval for least-squares mean difference (between any two study lens types) in microsphere clearance. Equivalence will be concluded if the upper limit is less than 10% and the lower limit is greater than -10%.

14.6. Secondary Analysis of Microsphere Uptake and Clearance by Lens Movement, Corneal Curvature and Blink Rate

Study the association between microsphere uptake/clearance and the following factors: lens movement, corneal curvature, and blink rate.

14.7. Other Exploratory Analyses

Not Applicable.

14.8. Interim Analysis

No interim analysis is planned.

14.9. Procedure for Handling Missing Data and Drop-Outs

Any missing, unused or spurious data will be outlined in the final study report. In each case, an explanation will be provided to outline why any data were missing or the rationale behind determining data to be unused or spurious. Given the feasibility nature of the project and the relatively small number of collected data points, all analyses will be conducted irrespective of any missing data.

14.10. Procedure for Reporting Deviations from Statistical Plan

The analysis will be conducted according to that specified in Section 14.1. There are no known reasons for which it is planned to deviate from these analysis methods. If for any reason a change is made, the change will be documented in the study report along with a justification for the change.

15. DATA HANDLING AND RECORD KEEPING/ARCHIVING

15.1. Electronic Case Report Form/Data Collection

The data for this study will be captured on electronic case report forms (eCRFs) using an EDC system [redacted] An authorized data originator will enter study data into the eCRFs using

the EDC system. Data collected on equipment that is not captured in EDC will be formatted to the specification of the JJVC database manager and sent to JJVC for analysis. Data generated from post hoc measurements (e.g. microsphere uptake and clearance data following image anaysis) will be collected on specific Microsoft Office Excel format worksheets at the clinical site and at the completion of the analysis transferred to JJVC biostatistician for data analysis in such format.

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

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

The content and structure of the eCRFs are compliant with ISO14155:2011.[1]

15.2. Subject Record

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

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

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

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

16. DATA MANAGEMENT

16.1. Access to Source Data/Document

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

16.2. Confidentiality of Information

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

16.3. Data Quality Assurance

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

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

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

17. MONITORING

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

- Ensuring that the investigation is being conducted according to the protocol, any subsequent amendments, and regulatory requirements are maintained
- Ensuring the rights and wellbeing of subjects are protected

- Ensuring adequate resources, including facilities, laboratories, equipment, and qualified clinical site personnel
- Ensuring that protocol deviations are documented with corrective action plans, as applicable
- Ensuring that the clinical site has sufficient test article and supplies
- Clarifying questions regarding the study
- Resolving study issues or problems that may arise
- Reviewing of study records and source documentation verification in accordance with the monitoring plan

18. ETHICAL AND REGULATORY ASPECTS

18.1. Study-Specific Design Considerations

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

18.2. Investigator Responsibility

The Principal Investigator is responsible for ensuring that the clinical study is performed in accordance with the signed agreement, the investigational plan, Section 4 of the ICH E6 guidelines on Good Clinical Practice (GCP),[2] and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles of the Declaration of Helsinki 64th WMA General Assembly 2013[3] and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with Section 8 of the ICH E6 guidelines on Good Clinical Practice (GCP),[2] and applicable regulatory requirements.

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

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

- Final protocol and, if applicable, amendments
- Sponsor-approved informed consent form (and any other written materials to be provided to the subjects)
- Investigator's Brochure (or equivalent information) and amendments
- Sponsor-approved subject recruitment materials
- Information on compensation for study-related injuries or payment to subjects for participation in the study

- Investigator's curriculum vitae, clinical licenses, or equivalent information (unless not required, as documented by IEC/IRB)
- Information regarding funding, name of the Sponsor, institutional affiliations, other potential conflicts of interest, and incentives for subjects
- Any other documents that the IEC/IRB requests to fulfill its obligation

This study will be undertaken only after IEC/IRB has given full approval of the final protocol, amendments (if any), the informed consent form, applicable recruiting materials, and subject compensation programs, and the Sponsor has received a copy of this approval. This approval letter must be dated and must clearly identify the documents being approved.

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

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

For protocol amendments that increase subject risk, the amendment and applicable informed consent form revisions must be submitted promptly to the IEC/IRB for review and approval before implementation of the change(s).

At least once a year, the IEC/IRB will review and reapprove this clinical study. This request should be documented in writing.

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

18.4. Informed Consent

Each subject must give written consent according to local requirements after the nature of the study has been fully explained. The consent form must be signed before performance of any

study-related activity. The consent form that is used must be approved by both the Sponsor and by the reviewing IEC/IRB. The informed consent is in accordance with principles that originated in the Declaration of Helsinki,[3] current ICH[2] and ISO 14155[1] guidelines, applicable regulatory requirements, and Sponsor Policy.

Before entry into the study, the Investigator or an authorized member of the clinical site personnel must explain to potential subject the aims, methods, reasonably anticipated benefits, and potential hazards of the study, and any discomfort it may entail. Subjects will be informed that their participation is voluntary and that they may withdraw consent to participate at any time.

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

18.5. Privacy of Personal Data

The collection, processing and disclosure of personal data and medical information related to the Study Subject, and personal data related to Principal Investigator and any clinical site personnel (e.g., name, clinic address and phone number, curriculum vitae) is subject to compliance with the General Data Protection Regulation[9] and other applicable personal data protection and security laws and regulations. Appropriate measures will be employed to safeguard these data, to maintain the confidentiality of the person's related health and medical information, to properly inform the concerned persons about the collection and processing of their personal data, to grant them reasonable access to their personal data and to prevent access by unauthorized persons.

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

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

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

- processed fairly and lawfully
- collected for specified, explicit, and legitimate purposes and not further processed in a way incompatible with these purposes

- adequate, relevant, and not excessive in relation to said purposes
- accurate and, where necessary, kept current

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

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

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

19. STUDY RECORD RETENTION

In compliance with the ICH/GCP guidelines,[2] the Investigator/Institution will maintain all CRFs and all subject records that support the data collected from each subject, as well as all study documents as specified in ICH/GCP[2] and all study documents as specified by the applicable regulatory requirement(s). The Investigator/Institution will take measures to prevent accidental or premature destruction of these documents.

Essential documents must be retained until at least two (2) years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least two (2) years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents will be retained for a longer period if required by the applicable regulatory requirements or instructed by the Sponsor. It is the responsibility of the Sponsor to inform the Investigator/Institution as to when these documents no longer need to be retained.

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

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

20. FINANCIAL CONSIDERATIONS

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

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

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

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

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

21. PUBLICATION

This study will be registered on ClinicalTrials.gov.

22. REFERENCES

1. ISO 14155:2011: Clinical Investigation of Medical Devices for Human Subjects — Good Clinical Practice. Available at: https://www.iso.org/standard/45557.html
2. International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP). Available at: http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
3. Declaration of Helsinki - Ethical principles for Medical Research Involving Human Subjects. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
4. Young G, Hunt C, Jones S. *Final Report* [redacted] *Clinical evaluation of silicone hydrogel lenses in 7-day extended wear.* October 11, 2012.
5. Polystyrene Microspheres IB v7.0.
6. Read ML. *Clinical Study Report* [redacted] *Use of microspheres to simulate particulate exchange in the post-lens tear film during contact lens wear*. February 23, 2015.
7. United States (US) Code of Federal Regulations (CFR). Available at: https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR
8. *Health Information Portability and Accountability Act (HIPAA).* Available at: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html
9. General Data Protection Regulation. Available at: https://www.eugdpr.org/
10. Kenward , M. G. , Roger , J. H. (1997). *Small sample inference for fixed effects from restricted maximum likelihood. Biometrics* 53: 983 – 997.

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APPENDIX A: PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

APPENDIX B: PATIENT INSTRUCTION GUIDE

PATIENT INSTRUCTION GUIDE

Clinic Only Wear

Soft (hydrophilic) Contact Lenses

Study CR-6291

TABLE OF CONTENTS

INTRODUCTION

About This Booklet:

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

For your eye health, it is important that your contact lenses be worn only as directed by your Study Investigator. Your Study Investigator should be kept fully aware of your medical. He or she will review with you all instructions for lens handling. This booklet will reinforce those instructions.

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

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

About Your Lenses and Contact Lens Wear:

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

Your study contact lenses should be worn at the study site according to the wearing schedule prescribed by your Study Investigator. You should always have your regular glasses or contact lenses available.

SYMBOLS KEY

The following symbols may appear on the label or packaging:

Symbol	*Description*
	Consult Instructions for Use
	Date of Manufacture
	Manufactured by or in
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CYL	Cylinder
AXIS	Axis
LOW	Low ADD
MID	Medium ADD
HGH	HIGH ADD
	Quality System Certification Symbol
	UV-Blocking
	Fee Paid for Waste Management
	CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Store away from direct sunlight
	Do Not Re-Use (Single Use)

GLOSSARY OF COMMONLY USED TERMS

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

WEARING RESTRICTIONS & INDICATIONS

POTENTIAL BENEFITS

Benefits may include a thorough eye examination and advice on contact lenses. The overall results might not benefit you, but they will contribute towards the development of better contact lenses.

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

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

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

Your Study Investigator will determine your wearing schedule (how long you should wear your lenses while you are in the Clinic).

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

PARTICIPATION CRITERIA

Participants who are in this study will need to have healthy eyes, except for the need to correct their eyesight. You should not be in this study if any of the following apply to you:

- You are currently pregnant or lactating (producing breast milk).
- You have any systemic (whole body) disease (such as Sjögren's Syndrome), autoimmune disease (such as rheumatoid arthritis), or use of medication (such as chronic steroid use), which may interfere with contact lens wear.
- You have used topical medication, such as eye drops or ointment within 24 hours prior to the study visit.
- You have a history of anaphylaxis or severe allergy.
- You have any previous or planned (during the course of the study) ocular (eye) surgery (such as radial keratotomy, PRK, LASIK, etc.).
- You have participated in any contact lens or lens care product clinical trial within 14 days prior to study enrollment.
- You are an employee or immediate family member of clinical site (such as Investigator, Coordinator, Technician).
- You have any slit lamp findings of grade 3 or higher (e.g. corneal oedema, corneal neovascularization, tarsal abnormalities, conjunctival injection) or findings of < grade 3 which in the investigator's opinion would contraindicate contact lens wear.

POSSIBLE RISKS OR DISCOMFORTS RELATED TO THE STUDY

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

There are risks to using your own contact lenses (and related products) and as such, there are risks of participating in this study. The study contact lenses are CE marked - this means that they are approved for sale in the European Union. It is possible that the following may occur: pain, abrasion of the eye, the sensations of itching, burning or stinging, excessive tear production, unusual secretions, redness, reduced sharpness of vision, blurred vision, sensitivity to light or dry eyes. In rare instances, corneal ulcers, scarring, the growth of blood vessels into the cornea, temporary or permanent decreased vision, iritis or infections of the eye might occur. Further treatment may be required, and you may also be precluded from future contact lens wear. If you experience any of these, you should contact Eurolens Research as soon as possible by telephoning 0161 306 2132.

In order to examine the surface of your eyes, we will apply sodium fluorescein, a yellow dye which is routinely used in a contact lens examination. Major side effects from the use of sodium fluorescein are very rare, but there are currently five reports of anaphylaxis worldwide. Other rare side effects can include slight stinging on instillation and temporary blurred vision.

No major side effects have been reported from topical installation of the microsphere suspension onto the ocular surface. Possible side effects may include slight stinging on instillation and temporarily blurred vision.

Any benefit or assistance, which you would normally have access to, will not be withheld from you during the study. If new information becomes available during the course of the study that may affect your willingness to continue in the study, you will be informed.

PRECAUTIONS

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

General Precautions:

Always contact your Study Investigator before using any medicine in your eyes.

Be aware that certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness may cause dryness of the eye, increased lens awareness (feeling of the lens in the eye) or blurred vision. Always inform your Study Investigator if you experience any problems with your lenses while taking such medications.

Be aware that if you use oral contraceptives (birth control pills), you could develop changes in vision or comfort when wearing contact lenses.

As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Ask your Study Investigator about the recommended follow-up schedule.

Who Should Know That You are Wearing Contact Lenses:

Inform all of your doctors (Health Care Professionals) about being a contact lens wearer.

LENS HANDLING AND INSERTION

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

Step 1: Getting Started

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

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

Before you start:

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

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

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

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

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

Step 2: Opening the Packaging

Lens Package

Each lens comes in its own lens package designed specifically to keep it sterile while sealed.

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

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

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

   NEVER use tweezers or other tools to remove your lenses from the lens container.

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

Lens Handling Tips

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

  DO NOT touch the lens with your fingernails.

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

  ALWAYS handle lenses carefully and avoid dropping them.

Step 3: Placing the Lens on the Eye

Remember, always start with the same eye.

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

1. BE SURE THE LENS IS NOT INSIDE-OUT by following one of the following procedures:
   - Place the lens on the tip of your index finger and check its profile. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out.
   - Gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.
2. With the lens on your index finger, use your other hand to hold your upper eyelid so you won't blink.
3. Pull down your lower eyelid with the other fingers of your "inserting" hand.
4. Look up at the ceiling and gently place the lens on the lower part of your eye.
5. Slowly release your eyelid and close your eye for a moment.
6. Blink several times to center the lens.
7. Use the same technique when inserting the lens for your other eye.

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

Step 4: Checking Your Lenses

After you have successfully inserted your lenses, you should ask yourself:

- Do I see well?

- How do the lenses feel on my eyes?
- How do my eyes look?

If after placement of the lens, your vision is blurred, consult your Study Investigator.

Step 5: Centering the Lens

A lens, which is on the cornea (center of your eye), will very rarely move onto the white part of the eye during wear. This, however, can occur if insertion and removal procedures are not performed properly. To center a lens, follow either of these procedures:

- Close your eyelids and gently massage the lens into place through the closed lids.

OR

- Gently move the off-centered lens onto the cornea (center of your eye) while the eye is opened using finger pressure on the edge of the upper lid or lower lid.

LENS WEARING

While wearing your lenses, remember the following important precautions:

Hazardous Conditions

- If you use aerosol (spray) products, such as hair spray, while wearing lenses, keep your eyes closed until the spray has settled.
- **Never** rinse your lenses in water from the tap. There are two reasons for this:
  1. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
  2. You might lose your lens down the drain.

Lubricating/Rewetting Solutions

- Your Study Investigator may recommend a lubricating/rewetting solution for your use. These solutions can be used to wet (lubricate) your lenses while you are wearing them.
- **Do not** use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

Sticking (Non-Moving) Lens

- For your eye health, it is important the lens moves freely on your eye.
- If the lens sticks (stops moving) on your eye, you should immediately consult your Study Investigator.

Sharing Lenses

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

Adhering to the Prescribed Wearing Schedules

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

REMOVING YOUR LENSES

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

Always remove the same lens first.

1. Wash, rinse and dry your hands thoroughly. You should follow the method that is recommended by your Study Investigator. Below is an example of one method: the Pinch Method.

   Pinch Method:

   Step 1. Look up, slide the lens to the lower part of the eye using the forefinger.

   Step 2. Gently pinch the lens between the thumb and forefinger.

   Step 3. Remove the lens.

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

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

Always have your regular glasses or contact lenses available.

EMERGENCIES

If chemicals of any kind (household products, laboratory chemicals, etc.) are splashed into your eyes: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONSULT YOUR STUDY INVESTIGATOR.

NOTES

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APPENDIX C: PACKAGE INSERT (APPROVED PRODUCT)

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

WICHTIG: Diese Gebrauchsinformation bitte sorgfältig lesen und für den künftigen Gebrauch aufbewahren

BELANGRIJK: lees deze informatie zorgvuldig door en bewaar deze voor toekomstig gebruik

ÖNEMLİ: Lütfen dikkatle okuyun ve daha sonra kullanmak üzere bu bilgileri saklayın

ACUVUE®
Brand Contact Lenses

Package Insert/ Packungsbeilage / Productbijlage / Prospektüs

CE
0086

English

Important: Please read carefully and keep this information for future use. This Package Insert is intended for the Eye Care Professional, but should be made available to patients upon request. This insert contains important information about the correct usage of ACUVUE® Brand Contact Lenses, which are listed in Table 1 and contains information about adverse reactions and contraindications.

Johnson & Johnson Medical Ltd provides ACUVUE® Brand Contact Lenses Patient Instruction Guides that contain further information for contact lens wearers. The Eye Care Professional should provide the patient with the Patient Instruction Guide that pertains to the patient's prescribed lens.

Table 1

Lens type and Brand name	Intended Use & Wear Schedule: Daily Wear - Daily disposable	Intended Use & Wear Schedule: Daily wear Frequent replacement	Intended Use & Wear Schedule: Extended wear	Inside-out indicator	Material	Polymer/water content (%)	Packaging Solution
ACUVUE® Brand Spherical Contact Lenses - Visibility Tinted with UV Blocker							
ACUVUE®2® Brand Contact Lenses		⊙	⊙	123	etafilcon A	42/58	❶
1•DAY ACUVUE® Brand Contact Lenses	⊙			123	etafilcon A	42/58	❶
1•DAY ACUVUE® MOIST Brand Contact Lenses	⊙			123	etafilcon A	42/58	❸
ACUVUE® ADVANCE® Brand Contact Lenses with HYDRACLEAR®		⊙		123	galyfilcon A ❹	53/47	❷
ACUVUE OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS		⊙	⊙	123	senofilcon A ❹	62/38	❷
ACUVUE OASYS® Brand Contact Lenses with HydraLuxe™	⊙			123	senofilcon A ❹	62/38	❷
1•DAY ACUVUE® TruEye® Brand Contact Lenses	⊙			123	narafilcon A ❹	54/46	❷
ACUVUE® ADVANCE® PLUS Brand Contact Lenses with HYDRACLEAR®		⊙		123	galyfilcon A ❹	53/47	❷
1•DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON®	⊙				etafilcon A	42/58	❸
ACUVUE® Vita™ Brand Contact Lenses		⊙		123	senofilcon C ❹	59/41	❷
ACUVUE® Brand Contact Lenses for ASTIGMATISM - Visibility Tinted with UV Blocker							
1•DAY ACUVUE® MOIST Brand Contact Lenses for ASTIGMATISM	⊙				etafilcon A	42/58	❸
1•DAY ACUVUE® Brand Contact Lenses for ASTIGMATISM	⊙				etafilcon A	42/58	❶
ACUVUE OASYS® Brand Contact Lenses for Astigmatism with HydraLuxe™	⊙				senofilcon A ❹	62/38	❷
ACUVUE® ADVANCE® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR®		⊙			galyfilcon A ❹	53/47	❷
ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS		⊙	⊙		senofilcon A ❹	62/38	❷
ACUVUE® Vita™ Brand Contact Lenses for ASTIGMATISM		⊙			senofilcon C ❹	59/41	❷
ACUVUE® Brand Contact Lenses for PRESBYOPIA - Visibility Tinted with UV Blocker							
ACUVUE® BIFOCAL Brand Contact Lenses		⊙	⊙	123	etafilcon A	42/58	❶
ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA with HYDRACLEAR® PLUS		⊙	⊙		senofilcon A ❹	62/38	❷
1•DAY ACUVUE® MOIST Brand Contact Lenses MULTIFOCAL	⊙			123	etafilcon A	42/58	❸

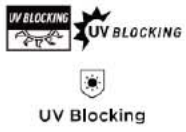
Key

Packaging Solution: ❶ Buffered saline ❷ Buffered saline with methyl ether cellulose ❸ Buffered saline with povidone.
Material content: ❹ Lens material contains silicone and meets Class 1 UV absorbing standards with transmissibility of less than 1% UVB (280-315nm) and 10% UVA (316-380nm) radiation. All etafilcon A products meet Class 2 UV absorbing standards with transmissibility of less than 5% UVB and 50% UVA radiation.

Symbols Key

The following symbols may appear on the label or packaging of your ACUVUE® Brand Contact Lenses

SYMBOL	DEFINITION
	Consult Instructions Leaflet
	Manufactured by or in
	Date of Manufacture
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
	Do Not Re-Use (Single Use)
DIA	Diameter
BC	Base Curve
D	Dioptre (lens power)
CYL	Cylinder
AXIS	Axis
MAX ADD	Highest near addition that can be corrected
LOW	"Low" near ADD (+0.75 to +1.25 ADD)
	Authorized Representative in the European Community

SYMBOL	DEFINITION
MID	"Mid" near ADD (+1.50 to +1.75 ADD)
HGH	"High" near ADD (+2.00 to +2.50 ADD)
S_H	NATURAL SHIMMER™
S_P	NATURAL SPARKLE™
N	NATURAL SHINE™
	Quality System Certification Symbol
	UV-Blocking
	Fee Paid for Waste Management
	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)
	"Identification mark" for paper containers and wrapping
	"Identification mark" for composite materials

CONTENT

ACUVUE® Brand Contact Lenses are provided in sterile individual blister packages, with the lens immersed in buffered saline solution (see **Table 1** for Packaging Solution). **DO NOT USE** if the sterile blister package is opened or damaged.

INTENDED USE

ACUVUE® Spherical Brand Contact Lenses

Are intended for Daily Wear or Extended Wear, as shown in **Table 1,** for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may have 1.00D or less of astigmatism.

1•DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON® are also intended to enhance or alter the appearance of the eye.

ACUVUE® Brand Contact Lenses for Astigmatism

Are intended for Daily Wear or Extended Wear, as shown in **Table 1,** for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may have astigmatism.

ACUVUE® Brand Contact Lenses for Presbyopia

Are intended for Daily Wear or Extended Wear, as shown in **Table 1,** for the optical correction of refractive ametropia (myopia and hyperopia) in presbyopic, phakic or aphakic persons with non-diseased eyes who have 0.75D or less of astigmatism.

Additionally, ACUVUE OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS are also indicated for therapeutic use as a bandage lens for the following acute and chronic ocular conditions:

- For corneal protection in lid and corneal abnormalities such as entropion, trichiasis, tarsal scars and recurrent corneal erosion. In addition, they are indicated for protection where sutures or ocular structure malformation, degeneration or paralysis may result in the need to protect the cornea from exposure or repeated irritation.
- For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, and post-keratoplasty.

- For use as a barrier during the healing process of epithelial defects such as chronic epithelial defects, corneal ulcer, neurotrophic and neuroparalytic keratitis, and chemical burns.
- For post surgical conditions where bandage lens use is indicated such as post refractive surgery, lamellar grafts, corneal flaps, and additional ocular surgical conditions.
- For structural stability and protection in piggy back lens fitting where the cornea and associated surfaces are too irregular to allow for corneal rigid gas permeable (RGP) lenses to be fitted. In addition, the use of the lens can prevent irritation and abrasions in conditions where there are elevation differences in the host/graph junction or scar tissue.

ACUVUE OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS when prescribed for therapeutic use may be worn for Daily Wear or Extended Wear.

All ACUVUE® Brand Contact Lenses have UV Blocking to help provide protection against transmission of harmful UV radiation to the cornea and into the eye.

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

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

WEAR SCHEDULE

The wearing and replacement schedule should be determined by the Eye Care Professional. Patients may tend to over wear the lenses initially. The Eye Care Professional should emphasise the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

Daily Wear - Daily Disposable

ACUVUE® Brand Contact Lenses prescribed for Daily Wear - Daily Disposable (less than 24 hours, while awake) as shown in **Table 1,** are intended to be worn once on a daily disposable basis and are to be discarded upon removal. **When used in this way, no cleaning or disinfection is required.**

1•DAY ACUVUE® TruEye® Brand Contact Lenses have not been developed for use with contact lens cleaners or disinfection systems. Lenses should be discarded after use. Start each wearing period with a fresh new lens.

Daily Wear - Frequent Replacement

All ACUVUE® Vita™ Brand Contact Lenses prescribed for Daily Wear – Frequent Replacement (less than 24 hours, while awake) as shown in Table 1, are to be discarded and replaced every month.

All other ACUVUE® Brand Contact Lenses prescribed for Daily Wear - Frequent Replacement, are to be discarded and replaced every two weeks.

All ACUVUE® Brand Contact Lenses as shown in **Table 1,** under the heading of Daily Wear - Frequent Replacement are to be cleaned, rinsed and disinfected each time the lens is removed using a chemical disinfection system only.

Extended Wear

ACUVUE® Brand Contact Lenses prescribed for Extended Wear, (greater than 24 hours, including while asleep) as shown in **Table 1,** may be used continuously for up to 7 days/6 nights and should be discarded upon removal. When used in this way, **no cleaning or disinfection is required.**

It is recommended that the new contact lens wearer first be evaluated on a Daily Wear - Frequent Replacement schedule. If in the opinion of the Eye Care Professional, the patient is determined to be an acceptable Extended Wear candidate, the Eye Care Professional is encouraged to determine a wear schedule based upon the response of the patient.

Once removed, it is recommended that the lens remains out of the eye for a period of rest overnight or longer. The Eye Care Professional should examine the patient during the early stages of Extended Wear.

CONTRAINDICATIONS

DO NOT USE ACUVUE® Brand Contact Lenses when any of the following conditions exist, when prescribing for refractive ametropia use.

- Acute or subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids.
- Severe insufficiency of lacrimal secretion (dry eye).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or Thimerosal in a solution which is to be used to care for the lenses prescribed on a frequent replacement wear schedule.
- Any active corneal infection (bacterial, fungal, protozoal or viral).
- If eyes become red or irritated.

For THERAPEUTIC USE, the Eye Care Professional may prescribe ACUVUE OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS, to aid in the healing process of certain ocular conditions, which may include those cited above.

WARNINGS

(Daily Wear = less than 24 hours, while awake; Extended Wear = greater than 24 hours, including while asleep).
Proper use and care of contact lenses and lens care products, including lens cases, are essential for safe use. Problems from wearing contact lenses or using lens care products could result in serious injury to the eye.
Patients should be advised of the following warnings pertaining to contact lens wear:

- ACUVUE® Brand Daily Disposable Contact Lenses are prescribed for daily wear and are for single use. Studies have shown that daily disposable soft contact lens wear reduces the risk of some complications including discomfort and inflammation that are associated with lens care and handling, and reuse can put you at greater risk of these problems.
- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products.†
- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Studies have shown that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users.

- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is greater than among those who do not wear them overnight.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- Studies have shown that the risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.
- Do not expose contact lenses to water during swimming, other water sports or bathing as this could increase the risk of serious eye infection from microorganisms which could lead to vision loss. If lenses have been submersed in water, the patient should discard and replace them with a new pair. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any activity involving water.

If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems are experienced, they should be instructed to immediately remove their lenses and the wearer should promptly contact their Eye Care Professional. It is recommended that contact lens wearers should see their Eye Care Professional routinely as directed.

† New England Journal of Medicine, September 21, 1989, 321 (12), pp. 773-783

PRECAUTIONS

What to do if problems occur

PLEASE ADVISE YOUR PATIENT TO REMOVE CONTACT LENSES IMMEDIATELY AND SEEK ADVICE FROM THEIR EYE CARE PROFESSIONAL.

Special Precautions for Eye Care Professionals

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

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

- Due to the reduction in light transmittance with cosmetically tinted lenses some patients may experience visual symptoms while wearing *1•DAY* ACUVUE® DEFINE® Brand Contact Lenses with LACREON®. In addition, some patients may experience peripheral awareness due to the opaque iris pattern.
- Patients who wear the ACUVUE® Brand Contact Lenses to correct presbyopia using monovision or multifocal correction may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.
- Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions.

Handling Precautions

- Before leaving the Eye Care Professional's office, the patient should be able to put on and promptly remove lenses or should have someone else available who can do this for them.
- **DO NOT** use if the sterile blister package is opened or damaged.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup.
- 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, cleaning, disinfecting, storing and wearing instructions in the "Patient Instruction Guide" for ACUVUE® Brand Contact Lenses and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container. Carefully remove the lens by sliding it up the side of the container.
- Do not touch the lens with fingernails.
- Close supervision is necessary for the Therapeutic use of all ACUVUE OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS. Ocular medications used during treatment with a bandage lens should be closely monitored by the Eye Care Professional. In certain ocular conditions, only the Eye Care Professional will insert and remove the lenses. In these cases, patients should be instructed not to handle the lenses themselves.

Lens Wearing Precautions

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "Care for a Sticking Lens". The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapours and fumes while wearing lenses.
- Never allow anyone else to wear your lenses. Sharing lenses greatly increases the chances of eye infections.
- After the recommended wearing schedule, always discard lenses worn as prescribed by the Eye Care Professional.

Solution Precautions

- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
- The patient should not change solutions without consulting their Eye Care Professional.
- Never use solutions recommended for rigid gas permeable (RGP) contact lenses.
- Always use fresh, unexpired lens care solutions and lenses.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage ACUVUE® Brand Contact Lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions in "Care for a Dried Out (Dehydrated) Lens" if lens surface does become dried out.

Lens Case Precautions

Lens cases can be a source of bacterial growth and require proper use, cleaning and replacement at regular intervals as recommended by the lens case manufacturer or Eye Care Professional.

Other Topics to Discuss with Patients

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

Who Should Know That the Patient is Wearing Contact Lenses?

- Inform all of your doctors (Health Care Professional) about being a contact lens wearer.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur when wearing ACUVUE® Brand Contact Lenses:

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

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

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

If the patient reports any problems, he or she should be instructed to **IMMEDIATELY REMOVE THE LENS.** If the discomfort or problem stops, the patient should then look closely at the lens. If the lens is in any way damaged, the patient **SHOULD NOT** put the lens back on the eye. The patient should discard the lens and apply a new fresh lens on the eye**.**

If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, he or she should be instructed to dispose of the lens and apply a new fresh lens. If the problem continues, the patient **SHOULD NOT** put the lens back on the eye but **IMMEDIATELY CONSULT HIS OR HER EYE CARE PROFESSIONAL.**

The patient should also be instructed **NOT** to use a new lens as self-treatment for the problem. The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. The patient should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

During therapeutic use an adverse effect may be due to the original disease or injury or may be due to the effects of wearing a contact lens. There is a possibility that the existing disease or condition might become worse when a soft contact lens for therapeutic use is used to treat an already diseased injured eye. The patient should be instructed to avoid serious eye damage by contacting the Eye Care Professional **IMMEDIATELY** if there is an increase in symptoms while wearing the lens.

Lens care directions

When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions in accordance with the individual patient's lens type and wearing schedule. The Eye Care Professional should recommend an appropriate care system tailored to the patient's individual requirements.

Failure to follow the correct lens care regime may result in serious injury to the eye, as described in the section entitled – **"Warnings"**
For complete information concerning contact lens handling, care, cleaning, disinfecting and storage, refer to the Patient Instruction Guide for ACUVUE® Brand Contact Lenses.

When ACUVUE® Brand Contact Lenses are recommended for frequent replacement, as shown in **Table 1**, the lenses must be cleaned and disinfected following removal before re-use. The lenses may be disinfected using a chemical disinfection system only (e.g. multi-purpose or hydrogen peroxide system).

The Eye Care Professional should review with the patient lens care directions, including basic information on lens case cleaning as well as specific instructions on the lens care regimen recommended for the patient. Since some lens materials contain silicone, as shown in **Table 1,** the wettability may differ when different lens care products are used.

Care for a sticking (non-moving) lens

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

Care for a dried out (dehydrated) lens

If any ACUVUE® Lens is off the eye for a prolonged period, its surface may become dry and gradually become non-wetting. If this should occur, discard the lens and use a new one.

EMERGENCIES

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

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing ACUVUE® Brand Contact Lenses or experienced with the lenses should be reported to:

Johnson & Johnson Medical Limited
Pinewood Campus
Nine Mile Ride
Wokingham
RG40 3EW
United Kingdom
Tel: 0800 022 4222 Fax: 0800 783 7029
E-mail: ukcs@visgb.jnj.com

Additional information

For additional information concerning ACUVUE® Brand Contact Lenses and to order your free copy of ACUVUE® Brand Contact Lenses Patient Instruction Guides, please contact the address shown above.

Manufactured by:

Please refer to carton for site of manufacture

USA:
Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville
Florida, 32256
USA

IRELAND:
Johnson & Johnson Vision Care (Ireland)
The National Technology Park
Limerick
Ireland

EU Authorised Representative:
Johnson & Johnson Medical Limited
Pinewood Campus
Nine Mile Ride
Wokingham
RG40 3EW
United Kingdom
www.acuvue.com

Deutsch

Wichtig: Diese Gebrauchsinformation sorgfältig lesen und für den künftigen Gebrauch aufbewahren. Diese Packungsbeilage richtet sich an Kontaktlinsenanpasser, sollte jedoch auf Nachfrage auch Kontaktlinsenträgern zur Verfügung gestellt werden. Diese Packungsbeilage enthält wichtige Informationen zum richtigen Gebrauch von ACUVUE® Kontaktlinsen, die in Tabelle 1 aufgeführt sind, und enthält Informationen über Nebenwirkungen und Gegenanzeigen.

Johnson & Johnson bietet Ratgeberbroschüren zu ACUVUE® Kontaktlinsen an, die weitere Hinweisen für Kontaktlinsenträger enthalten. Der Kontaktlinsenanpasser muss dem Kontaktlinsenträger die entsprechenden Informationen für die Kontaktlinsen überreichen.

Tabelle 1

Kontaktlinsentyp und Markenname	Verwendungszweck & Tragemodus			Handhabungs markierung	Material	Polymer-/ Wasser-gehalt (%)	Verpackungslösung
	Tagestragen - Einmaliger Gebrauch	Tagestragen - Wiederverwendbar	Verlängertes Tragen				
Sphärische ACUVUE® Kontaktlinsen - Handhabungstönung mit UV-Schutz							
ACUVUE®2® Kontaktlinsen		⊙	⊙	123	etafilcon A	42/58	❶
1•DAY ACUVUE® Kontaktlinsen	⊙			123	etafilcon A	42/58	❶
1•DAY ACUVUE® MOIST Kontaktlinsen	⊙			123	etafilcon A	42/58	❸
ACUVUE® ADVANCE® Kontaktlinsen with HYDRACLEAR®		⊙		123	galyfilcon A ❹	53/47	❷
ACUVUE OASYS® Kontaktlinsen with HYDRACLEAR® PLUS		⊙	⊙	123	senofilcon A ❹	62/38	❷
ACUVUE OASYS® Kontaktlinsen with HydraLuxe™	⊙			123	senofilcon A ❹	62/38	❷
1•DAY ACUVUE® TruEye® Kontaktlinsen	⊙			123	narafilcon A ❹	54/46	❷
ACUVUE® ADVANCE® PLUS Kontaktlinsen with HYDRACLEAR®		⊙		123	galyfilcon A ❹	53/47	❷
1•DAY ACUVUE® DEFINE® Kontaktlinsen with LACREON®	⊙				etafilcon A	42/58	❸
ACUVUE® Vita™ Kontaktlinsen		⊙		123	senofilcon C ❹	59/41	❷
Torische ACUVUE® Kontaktlinsen - Handhabungstönung mit UV-Schutz							
1•DAY ACUVUE® MOIST Kontaktlinsen for ASTIGMATISM	⊙				etafilcon A	42/58	❸
1•DAY ACUVUE® Kontaktlinsen for ASTIGMATISM	⊙				etafilcon A	42/58	❶
ACUVUE OASYS® Kontaktlinsen for Astigmatism with HydraLuxe™	⊙				senofilcon A ❹	62/38	❷
ACUVUE® ADVANCE® Kontaktlinsen for ASTIGMATISM with HYDRACLEAR®		⊙			galyfilcon A ❹	53/47	❷
ACUVUE OASYS® Kontaktlinsen for ASTIGMATISM with HYDRACLEAR® PLUS		⊙	⊙		senofilcon A ❹	62/38	❷
ACUVUE® Vita ™ for ASTIGMATISM Kontaktlinsen		⊙			senofilcon C ❹	59/41	❷
Mehrstärken ACUVUE® Kontaktlinsen - Handhabungstönung mit UV-Schutz							
ACUVUE® BIFOCAL Kontaktlinsen		⊙	⊙	123	etafilcon A	42/58	❶
ACUVUE OASYS® Kontaktlinsen for PRESBYOPIA with HYDRACLEAR® PLUS		⊙	⊙		senofilcon A ❹	62/38	❷
1•DAY ACUVUE® MOIST Kontaktlinsen MULTIFOCAL	⊙			123	etafilcon A	42/58	❸

Erläuterung:

Verpackungslösung: ❶ Gepufferte Kochsalzlösung ❷ Gepufferte Kochsalzlösung mit Methylether-Cellulose ❸ Gepufferte Kochsalzlösung mit Povidon

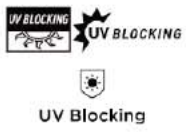
Material: ❹ Linsenmaterial enthält Silikon und erfüllt die Klasse 1 UV-Absorptionskriterien mit einer Transmissibilität von weniger als 1% UVB (280-315nm) und 10% UVA-Strahlung (316-380nm).

All etafilcon A Produkte erfüllen die Klasse 2 UV-Absorptionskriterien mit einer Transmissibilität von weniger als 5% UVB und 50% UVA-Strahlung.

Erläuterung der Symbole

Die folgenden Symbole können sich auf der Packung oder dem Blister Ihrer ACUVUE® Kontaktlinsen befinden.

SYMBOL	DEFINITION
	Gebrauchsinformation beachten
	Hergestellt von oder in
	Datum der Herstellung
	Verwendbar bis (Verfallsdatum)
	Chargennummer
	Sterilisation durch Dampf oder trockene Hitze
	Nicht zur Wiederverwendung (nur zum einmaligen Gebrauch)
DIA	Durchmesser
BC	Basiskurve
D	Kontaktlinsenwirkung (Dioptrien)
CYL	Zylinderwirkung (Dioptrien)
AXIS	Achse
MAX ADD	Höchster zu korrigierender Nahzusatz
LOW	„Geringe“ Addition (+0,75 bis +1,25 ADD)
	Bevollmächtigter in der EU

SYMBOL	DEFINITION
MID	„Mittlere“ Addition (+1,50 bis +1,75 ADD)
HGH	„Hohe“ Addition (+2,00 bis +2,50 ADD)
S_H	NATURAL SHIMMER™
S_P	NATURAL SPARKLE™
N	NATURAL SHINE™
	EU-Konformitätskennzeichen
	UV-Schutz
	Grüner Punkt
	HINWEIS: In den USA verschreibungspflichtig.
	Korrekte Ausrichtung der Linse
	Falsche Ausrichtung der Linse (Innenseite außen)
	„Kennzeichnung“ für Papierbehälter und Verpackung
	„Kennzeichnung“ für Verbundstoffe

INHALT

ACUVUE® Kontaktlinsen sind einzeln in gepufferter Kochsalzlösung in sterilen Blistern verpackt (Verpackungslösung: siehe **Tabelle 1**). **NICHT VERWENDEN,** wenn die sterile Blisterverpackung geöffnet oder beschädigt wurde.

VERWENDUNGSZWECK

Sphärische ACUVUE® Kontaktlinsen

Für Tagestragen (TT) und verlängertes Tragen (vT) gemäß **Tabelle 1**, zur Korrektur einer Fehlsichtigkeit (Kurz- und Weitsichtigkeit) am gesunden Auge bei Personen mit oder ohne Aphakie, für einen Astigmatismus bis 1,00 D.

1•DAY ACUVUE® DEFINE® with LACREON® sind auch geeignet, um das Aussehen der Augen zu verbessern oder zu verändern.

Torische ACUVUE® Kontaktlinsen

Für Tagestragen und verlängertes Tragen gemäß **Tabelle 1**, zur Korrektur einer Fehlsichtigkeit (Kurz- und Weitsichtigkeit) am gesunden Auge bei Personen mit oder ohne Aphakie, für einen Astigmatismus.

Mehrstärken ACUVUE® Kontaktlinsen

Für Tagestragen und verlängertes Tragen, wie in Tabelle 1 beschrieben, für die Korrektur brechungsbedingt fehlsichtiger Personen (Kurzsichtigkeit und Weitsichtigkeit) bestimmt, die entweder alterssichtig, linsenlos oder mit Intraokularlinsen ausgestattet sind und gesunde Augen mit einem Astigmatismus von maximal 0,75 D aufweisen.

Zusätzlich sind ACUVUE OASYS® Kontaktlinsen with HYDRACLEAR® PLUS auch als Verbandlinse für folgende akute und chronische Symptome angezeigt:

- Zum Schutz der Cornea bei lid- und cornealen Abnormitäten wie Entropium, Trichiasis, tarsalen Narben oder wiederkehrenden cornealen Erosionen. Zusätzlich sind sie auch dort angezeigt, wo Wundnähte, okuläre Fehlbildungen oder Lähmungen einen Schutz der Cornea vor Belastungen oder wiederholten Irritationen erforderlich machen.
- Zur cornealen Schmerzlinderung wie bei Keratopathia bullosa, epithelialer Erosion und Abrasion, Keratitis filamentosa und nach Keratoplastik.
- Zur Nutzung als Barriere während des Heilungsprozesses bei epithelialen Defekten wie chronischen epithelialen Defekten, ulzerativer Keratitis, neurotropher Keratopathie, neuroparalytischer Keratitis und Verätzungen.

- Zur Nachversorgung bei chirurgischen Eingriffen, bei denen ein Verbandlinsengebrauch angezeigt ist, wie nach refraktiver Chirurgie, lamellierender Keratoplastik, Hornhautlamellen und zusätzlichen augenchirurgischen Begleitumständen.
- Zur strukturellen Stabilisierung und zum Schutz bei Huckepack-Systemen, bei denen die Cornea und angeschlossene Oberflächen zu irregulär gestaltet sind und keine Anpassung mit einer formstabilen, gasdurchlässigen Kontaktlinse ermöglichen. Die Kontaktlinse kann zudem dazu beitragen, Reizungen und Abrasionen bei Profilunterschieden am Übergang zwischen Transplantat und Empfängerhornhaut oder an Narbengewebe zu lindern.

Die ACUVUE OASYS® Kontaktlinsen with HYDRACLEAR® PLUS für therapeutische Zwecke können für das Tagestragen oder für das verlängerte Tragen angepasst werden.

Alle ACUVUE® Kontaktlinsen sind mit einem UV-Schutz ausgestattet, der dazu beitragen kann, die Hornhaut und das Innere des Auges vor schädlicher UV-Strahlung zu schützen.

WARNUNG: UV-absorbierende Kontaktlinsen sind KEIN Ersatz für UV-absorbierende Brillen wie UV-absorbierende Schutzbrillen oder Sonnenbrillen, weil sie das Auge und den Augenbereich nicht vollständig abschirmen. Sie sollten daher weiterhin UV-absorbierende Brillen tragen.

Hinweis: Eine langfristige UV-Exposition der Augen gehört zu den Risikofaktoren für Grauen Star. Die Exposition ist von zahlreichen Faktoren abhängig. Zu diesen gehören Umweltfaktoren (Höhe, Geografie, Bewölkung) sowie persönliche Faktoren (Umfang und Art der Aktivitäten im Freien). Alle ACUVUE® Kontaktlinsen sind mit einem UV-Schutz ausgestattet, der dazu beiträgt, die Hornhaut und das Innere des Auges vor schädlicher UV-Strahlung zu schützen. Es wurden jedoch keine klinischen Studien durchgeführt, um den Nachweis zu erbringen, dass das Tragen von Kontaktlinsen mit UV-Schutz das Risiko von Grauem Star oder anderen Augenbeschwerden reduziert. Wenden Sie sich an Ihren Kontaktlinsenanpasser, um ausführlichere Informationen zu erhalten.

TRAGEMODUS

Der Tragemodus und Austauschrhythmus muss durch den Kontaktlinsenanpasser festgelegt werden. Kontaktlinsenträger neigen manchmal dazu, die Kontaktlinsen anfangs zu lange zu tragen. Der Kontaktlinsenanpasser sollte dem Kontaktlinsenträger verdeutlichen, wie wichtig die exakte Einhaltung des anfänglichen maximalen Tragemodus ist. Auch regelmäßige Kontrollen durch den Kontaktlinsenanpasser sind von größter Bedeutung.

Tagestragen - Kontaktlinsen für den einmaligen Gebrauch

Die ACUVUE® Kontaktlinsen sollten beim Tagestragen für den einmaligen Gebrauch (weniger als 24 Stunden im Wachzustand) gemäß **Tabelle 1** nur einmal getragen und täglich nach dem Abnehmen entsorgt werden. **In diesem Fall ist keine Reinigung oder Desinfektion erforderlich.**

1•DAY ACUVUE® TruEye® Kontaktlinsen sind nicht für die Nutzung von Kontaktlinsenpflegemitteln und Desinfektionssystemen entwickelt worden. Die Linsen sollten nach dem Gebrauch entsorgt werden. Starten Sie jede Trageperiode mit einer neuen Linse.

Wiederverwendbare Kontaktlinsen zum Tagestragen

Alle ACUVUE® Vita™ Kontaktlinsen zum Tagestragen (weniger als 24 Stunden im Wachzustand), wie in **Tabelle 1** beschrieben, müssen jeden Monat entsorgt und ausgetauscht werden.

Alle anderen wiederverwendbaren ACUVUE® Kontaktlinsen zum Tagestragen müssen alle zwei Wochen entsorgt und ausgetauscht werden.

Alle ACUVUE® Kontaktlinsen gemäß **Tabelle 1** (Spaltenüberschrift Tagestragen – Wiederverwendbar) müssen nach jedem Abnehmen mit einem chemischen Pflegesystem gereinigt, abgespült und desinfiziert werden.

Verlängertes Tragen

ACUVUE® Kontaktlinsen zum verlängerten Tragen (länger als 24 Stunden, also auch über Nacht) gemäß **Tabelle 1** können kontinuierlich bis zu 7 Tagen/6 Nächten getragen werden und müssen nach dem Abnehmen entsorgt werden. **Eine Reinigung oder Desinfektion ist hierbei nicht erforderlich**.

Der Kontaktlinsenanpasser sollte zunächst im Rahmen des Tagestragens von wiederverwendbaren Kontaktlinsen feststellen, ob das verlängerte Tragen für den Kontaktlinsenträger in Frage kommt. Ist dies der Fall, sollte der Kontaktlinsenanpasser den Tragemodus individuell auf den Kontaktlinsenträger abstimmen.

Nach dem Abnehmen sollen mindestens über Nacht keine neue Kontaktlinsen aufgesetzt werden. Der Kontaktlinsenanpasser sollte den Kontaktlinsenträger in der Anfangszeit häufiger kontrollieren.

GEGENANZEIGEN

KEINE ACUVUE® Kontaktlinsen zur Korrektur einer Fehlsichtigkeit anpassen, wenn mindestens eines der nachstehend genannten Symptome des Auges oder Augenlids vorliegt.

- Akute oder subakute Entzündung oder Infektion der Vorderkammer des Auges.
- Alle Erkrankungen, Verletzungen oder Anomalien von Hornhaut, Bindehaut oder Augenlidern.
- Schwere Verminderung der Tränensekretion (trockene Augen).
- Hypästhesie der Hornhaut (verminderte Hornhautempfindlichkeit).
- Jegliche systemische Erkrankung mit Auswirkungen auf das Auge, die durch Kontaktlinsen verstärkt werden kann.
- Allergische Reaktionen der Augenoberfläche oder Augenumgebung, die durch das Tragen von Kontaktlinsen oder den Gebrauch von Kontaktlinsen-Pflegemitteln ausgelöst oder verstärkt werden.
- Allergische Reaktion auf Inhaltsstoffe in Pflegelösungen, wie Quecksilber oder Thiomersal .
- Jegliche aktiven Hornhautentzündungen (Bakterien-, Pilz- oder Vireninfektion).
- Wenn die Augen rot oder gereizt sind.

ACUVUE OASYS® Kontaktlinsen with HYDRACLEAR® PLUS können auch zu THERAPEUTISCHEN ZWECKEN angepasst werden, um den Heilungsprozess bestimmter Symptome zu unterstützen (unter anderem die vorgenannten Symptome).

WARNUNGEN

(Tägliches Tragen = weniger als 24 Stunden im Wachzustand; verlängertes Tragen = länger als 24 Stunden, also auch über Nacht).
Die richtige Anwendung und Pflege der Kontaktlinsen sowie der richtige Gebrauch der Pflegeprodukte (u. a. die Reinigung des Aufbewahrungsbehälters) sind unerlässlich für die sichere Nutzung der Kontaktlinsen. Probleme beim Tragen der Kontaktlinsen oder beim Gebrauch der Pflegeprodukte können zu schweren Schädigungen am Auge führen.

Die Kontaktlinsenträger sind über die folgenden Warnungen hinsichtlich des Tragens von Kontaktlinsen zu informieren:

- ACUVUE® Ein-Tages Kontaktlinsen sind für den täglichen und einmaligen Gebrauch konzipiert. Studien haben gezeigt, dass weiche Tageslinsen das Risiko von einigen Komplikationen wie Diskomfort und Entzündungen, die mit der Linsenpflege und der

Handhabung verbunden sind, reduzieren. Ein Wiederverwenden kann ein erhöhtes Risiko für diese Probleme nach sich ziehen.

- Probleme beim Tragen der Kontaktlinsen oder beim Gebrauch der Pflegeprodukte können zu schweren Schädigungen am Auge führen. Die Kontaktlinsenträger sind darauf hinzuweisen, dass die richtige Anwendung und Pflege der Kontaktlinsen sowie der richtige Gebrauch der Pflegeprodukte (u. a. die Reinigung des Aufbewahrungsbehälters) unerlässlich für die sichere Nutzung der Kontaktlinsen sind.†
- Augenbeschwerden (z. B. Hornhautgeschwüre) können sich rasch entwickeln und zum Sehverlust führen.
- In Studien wurde festgestellt, dass das Risiko einer ulzerativen Keratitis bei Kontaktlinsenträgern im vT-Modus höher ist als im TT-Modus.
- Wenn TT-Träger die Kontaktlinsen über Nacht auf dem Auge belassen (entgegen dem freigegebenen Verwendungszweck dieser Linsen), ist das Risiko einer ulzerativen Keratitis höher als bei TT-Trägern, die die Kontaktlinsen bestimmungsgemäß nur am Tag tragen.
- Das Gesamtrisiko einer ulzerativen Keratitis kann durch sorgfältige Beachtung der Vorschriften für die Pflege der Kontaktlinsen und des Aufbewahrungsbehälters vermindert werden.
- In Studien wurde festgestellt, dass das Risiko einer ulzerativen Keratitis bei Kontaktlinsenträgern, die zugleich Raucher sind, höher ist als bei Nichtrauchern.
- Kontaktlinsen sollten beim Schwimmen, Baden oder bei Wassersportarten nicht mit dem Wasser in Berührung kommen, da dies das Risiko von schweren Augeninfektionen durch Mikroorganismen, die zu Sehverlust führen können, erhöht. Wenn Linsen mit Wasser in Berührung gekommen sind, sollten diese entsorgt und mit einem neuen Paar ersetzt werden. Der Kontaktlinsenspezialist sollte für Empfehlungen für das Tragen von Kontaktlinsen bei Wasseraktivitäten konsultiert werden.

Wenn Reizungen oder Rötungen des Auges, Änderungen des Sehvermögens oder andere Probleme auftreten, sollten die Kontaktlinsenträger die Kontaktlinsen sofort vom Auge nehmen und sich an ihren Kontaktlinsenanpasser wenden. Der Kontaktlinsenträger soll den Kontaktlinsenanpasser in regelmäßigen Abständen zur Kontrolle aufsuchen.

***† New England Journal of Medicine, September 21, 1989,* 321 (12), pp. 773-783**

VORSICHTSMAßNAHMEN

WEISEN SIE DEN KONTAKTLINSENTRÄGER AN, DIE KONTAKTLINSEN BEI AUFTRETENDEN PROBLEMEN SOFORT ZU ENTFERNEN UND SICH AN DEN KONTAKTLINSENANPASSER ZU WENDEN.

Besondere Vorsichtsmaßnahmen für Kontaktlinsenanpasser

Aufgrund der geringen Anzahl von Patienten, die an klinischen Kontaktlinsen-Studien teilnehmen, wurden der Aufbau und die materialbedingten Linseneigenschaften, sowie sämtliche Stärkenparameter nicht in ausreichender Zahl bewertet. Daher sollte der Kontaktlinsenanpasser bei der Auswahl des Aufbaus und der Eigenschaften der Kontaktlinsen alle Linseneigenschaften berücksichtigen, die einen Einfluss auf die Leistungsfähigkeit der Linsen und die Augengesundheit haben können. Dazu gehören die Sauerstoffdurchlässigkeit, die Benetzbarkeit, zentrale und periphere Linsendicke sowie der Durchmesser der optischen Zone.

Der potentielle Einfluss dieser Faktoren auf die Augengesundheit des Patienten muss sorgfältig gegen die Notwendigkeit der Korrektur einer Fehlsichtigkeit abgewogen werden.

Daher müssen Augengesundheit und die Leistungsfähigkeit der Linsen durch den Kontaktlinsenanpasser sorgfältig überwacht werden.

- Durch die reduzierte Lichtdurchlässigkeit bei Kontaktlinsen mit Handhabungstönung können beim Tragen von *1•DAY* ACUVUE® DEFINE® mit LACREON® bei manchen Personen visuelle Symptome auftreten. Zudem können manche Kontaktlinsenträger aufgrund des opaken Irismusters die Farbe der Kontaktlinse wahrnehmen.
- Kontaktlinsenträger, die ACUVUE® Kontaktlinsen tragen und Ihre Alterssichtigkeit mittels monovision oder multifocal korrigieren, erreichen eventuell weder für die Nähe noch für die Ferne die optimale Sehqualität. Die Anforderungen an das Sehen sind individuell verschieden und müssen bei der Auswahl der optimalen Linsen für jeden Träger berücksichtigt werden.
- Fluorescein, ein gelber Farbstoff, darf nicht verwendet werden, solange sich die Kontaktlinsen auf dem Auge befinden. Die Kontaktlinsen können diesen Farbstoff aufnehmen und sich verfärben. Wenn sich Fluorescein auf den Augen befindet, sind die Augen mit einer für die Verwendung am Auge zugelassenen sterilen Kochsalzlösung zu spülen.
- Kontaktlinsenanpasser sollten den Kontaktlinsenträger anweisen, die Linsen sofort abzunehmen, wenn die Augen rot oder gereizt werden.
- Kontaktlinsenanpasser müssen Kontaktlinsenträger sorgfältig über folgende Pflegeanweisungen und Sicherheitsmaßnahmen informieren.

Vorsichtsmaßnahmen für die Verwendung

- Bevor Sie Ihren Kontaktlinsenanpasser verlassen, sollten Sie entweder selbst in der Lage sein, die Kontaktlinsen aufzusetzen und abzunehmen oder jemanden in der Nähe haben, der das für Sie tun kann.
- **NICHT VERWENDEN,** wenn die sterile Blisterverpackung geöffnet oder beschädigt wurde.
- Hände vor dem Anfassen der Linsen stets waschen und spülen. Kosmetika, Lotionen, Cremes, Deodorants, Sprays oder Seife dürfen nicht in die Augen oder auf die Kontaktlinsen gelangen. Die Kontaktlinsen am besten vor dem Auftragen von Make-up aufsetzen.
- Berühren Sie Kontaktlinsen nicht mir den Fingern oder Händen, wenn die Hände nicht frei von Fremdkörpern sind, da sonst mikroskopische Kratzer an den Linsen entstehen könnten, die ein verzerrtes Sehen und/oder Verletzungen am Auge hervorrufen könnten.
- Befolgen Sie sorgfältig die Handhabungsanweisungenzum Aufsetzen und Abnehmen, zur Reinigung, Desinfektion, Aufbewahrung und Trageempfehlung, die in den Handhabungs-ratgebern für ACUVUE® Kontaktlinsen beschrieben sind, die Sie von Ihrem Kontaktlinsenanpasser für die angepassten Kontaktlinsen ausgehändigt bekommen sollten.
- Behandeln Sie Kontaktlinsen stets sorgfältig und lassen Sie sie nicht fallen.
- Verwenden Sie niemals Pinzetten oder andere Werkzeuge, um Ihre Kontaktlinsen aus dem Kontaktlinsenbehälter zu entfernen. Entnehmen Sie die Kontaktlinse, indem Sie diese vorsichtig seitlich aus dem Behälter herausschieben**.**
- Berühren Sie die Kontaktlinsen nicht mit den Fingernägeln.
- Die therapeutische Verwendung aller ACUVUE OASYS® Kontaktlinsen with HYDRACLEAR® PLUS muss streng überwacht werden. Eine medikamentöse Behandlung des Auges während der Behandlung mit einer Verbandlinse muss vom Kontaktlinsenanpasser streng überwacht werden. Bei manchen Symptomen darf nur der Kontaktlinsenanpasser die Linsen aufsetzen und abnehmen. In diesen Fällen müssen die Patienten angewiesen werden, die Kontaktlinsen nicht selbst zu verwenden.

Vorsichtsmaßnahmen für das Tragen von Kontaktlinsen

- Wenn die Kontaktlinse zu fest auf dem Auge haftet, sich also nicht mehr bewegt, sollten unbedingt die Empfehlungen zur „Vorgehensweise bei einer festsitzenden Kontaktlinse" beachtet werden. Die Kontaktlinse muss sich auf dem Auge frei bewegen, um die Augengesundheit zu erhalten. Wenn die Kontaktlinse weiterhin nicht frei beweglich ist, sollte der Kontaktlinsenträger unverzüglich den Kontaktlinsenanpasser aufsuchen.
- Kontaktlinsen nie über einen längeren, als vom Kontaktlinsenanpasser, empfohlenen Zeitraum tragen.

- Wenn während des Tragens von Linsen Aerosolprodukte wie Haarspray verwendet werden, muss vorsichtig vorgegangen werden und die Augen geschlossen bleiben, bis sich das Spray verflüchtigt hat.
- Alle schädlichen oder reizenden Dämpfe oder Rauch müssen während des Tragens von Kontaktlinsen vermieden werden.
- Lassen Sie niemals andere Personen Ihre Kontaktlinsen tragen. Der Austausch von Kontaktlinsen zwischen verschiedenen Personen führt zu einem erhöhten Risiko von Augeninfektionen.
- Entsorgen Sie Kontaktlinsen nach dem empfohlenen Tragemodus stets gemäß den Empfehlungen des Kontaktlinsenanpassers.

Vorsichtsmaßnahmen für Pflegemittel

- Verschiedene Kontaktlinsen-Pflegemittel können nicht immer zusammen verwendet werden, und nicht alle Mittel sind zum sicheren Gebrauch mit allen Kontaktlinsen geeignet. Verwenden Sie nur empfohlene Kontaktlinsen-Pflegemittel.
- Wechseln Sie nie Ihre Pflegemittelmarke ohne vorherige Konsultation Ihres Kontaktlinsenspezialisten.
- Verwenden Sie nie Pflegemittel, die für harte Kontaktlinsen (formstabile Kontaktlinsen) empfohlen werden.
- Verwenden Sie stets frische Kontaktlinsen-Pflegemittel und Kontaktlinsen, die das Verfallsdatum nicht überschritten haben.
- Befolgen Sie beim Gebrauch von Kontaktlinsen-Pflegemitteln stets die Anweisungen der Packungsbeilage.
- Verwenden Sie ausschließlich chemische Kontaktlinsen-Pflegesysteme (keine Sterilisation durch Hitze). Die Verwendung eines Pflegesystems, das Wärme verwendet (thermische Desinfektion) kann ACUVUE® Kontaktlinsen beschädigen.
- Sterile, nicht konservierte Pflegemittel müssen nach Gebrauch entsprechend dem Zeitraum entsorgt werden, der in den Anweisungen angegeben ist.
- Verwenden Sie keinesfalls Spucke oder andere als die empfohlenen Mittel, um die Kontaktlinsen zu benetzen.
- Die Kontaktlinsen müssen stets vollständig von der empfohlenen Aufbewahrungslösung bedeckt sein, wenn sie nicht getragen werden (Aufbewahrung). Eine längere Austrocknung reduziert die Benetzbarkeit der Kontaktlinsenoberfläche. Befolgen Sie die Anweisungen zur Pflege der Kontaktlinsen in „Vorgehensweise bei einer ausgetrockneten (dehydrierten) Kontaktlinse“, wenn die Linsenoberfläche ausgetrocknet ist.

Vorsichtsmaßnahmen für den Aufbewahrungsbehälter

Aufbewahrungsbehälter für Kontaktlinsen können Bakterienwachstum verursachen und erfordern korrekte Verwendung, Reinigung und Austausch in regelmäßigen Abständen,

gemäß den Empfehlungen des Herstellers des Aufbewahrungsbehälters oder des Kontaktlinsenanpassers.

Andere Themen zur Diskussion mit Kontaktlinsenträgern

- Wenden Sie sich stets an den Augenarzt, bevor Sie die Augen medikamentös behandeln oder Augentropfen benutzen.
- Bestimmte Medikamente, beispielsweise Antihistamine, Dekongestiva, Diuretika, Muskelrelaxanzien, Tranquilizer und Mittel gegen Reisekrankheit, können eine Austrocknung der Augen, ein verstärktes Fremdkörpergefühl und verschwommenes Sehen zur Folge haben. In diesen Fällen sind geeignete Gegenmaßnahmen zu ergreifen.
- Bei Kontaktlinsenträgerinnen, die ein Empfängnisverhütungsmittel einnehmen, können Sehqualitätsschwankungen auftreten und/oder die Verträglichkeit der Kontaktlinsen verändern. Patienten müssen darauf hingewiesen werden.
- Wie bei allen Kontaktlinsen sind regelmäßige Kontrollen notwendig, um die Augengesundheit des Patienten sicherzustellen. Der Patient muss über einen empfohlenen Nachsorgeplan informiert werden.

Wer sollte wissen, dass der Patient Kontaktlinsen trägt?

- Informieren Sie alle Ihre Ärzte darüber, dass Sie Kontaktlinsen tragen.
- Informieren Sie Ihren Arbeitgeber in jedem Fall darüber, dass Sie Kontaktlinsen tragen. Bei bestimmten Tätigkeiten ist das Tragen einer Schutzbrille vorgeschrieben bzw. das Tragen von Kontaktlinsen untersagt.

NEBENWIRKUNGEN

Der Patient ist zu informieren, dass beim Tragen von ACUVUE® Kontaktlinsen die folgenden Probleme auftreten können:

- Das Auge kann brennen, stechen und/oder jucken.
- Das Auge kann gereizter sein als beim ersten Aufsetzen der Kontaktlinsen.
- Es kann sich so anfühlen, als ob Sie etwas im Auge hätten (Fremdkörper, Kratzer).
- Unter Umständen können periphere Infiltrate, periphere Hornhautgeschwüre und Erosion der Hornhaut zu vorübergehenden Beeinträchtigungen führen. Es können auch weitere physiologische Veränderungen auftreten, beispielsweise lokale oder generalisierte Ödeme, Symptome von trockenen Augen, Neubildung von Gefäßen in der Hornhaut, Hornhautverfärbungen, Gefäßinjektionen, Anomalien der Lidbindehaut, Entzündung der Regenbogenhaut oder Bindehautentzündung, die bei geringer Ausprägung klinisch akzeptabel sind.

- Starker Tränenfluss, eine ungewöhnliche Sekretbildung oder eine Rötung der Augen können ebenfalls auftreten.
- Verminderte Sehschärfe, verschwommenes Sehen, Wahrnehmungsstörungen, Farbsäume um Objekte und Personen, Photophobie oder trockene Augen können ebenfalls auftreten, wenn die Kontaktlinsen kontinuierlich oder zu lange getragen werden.

Der Patient sollte angewiesen werden, mindestens einmal täglich einen 3-Punkte-Selbsttest durchzuführen. Er Sollte sich folgende Fragen stellen:

- Wie fühlen sich die Kontaktlinsen auf meinen Augen an?
- Wie sehen meine Augen aus?
- Habe ich eine Änderung der Sehqualität festgestellt?

Berichtet der Kontaktlinsenträger über eines der Probleme, sollte er angewiesen werden, **DIE LINSE SOFORT ABZUNEHMEN.** Verschwinden die Beschwerden oder das Problem, sollte der Kontaktlinsenträger sich die Kontaktlinse genau ansehen. Wenn die Kontaktlinse in irgendeiner Art beschädigt ist, soll der Kontaktlinsenträger diese **NICHT** wieder aufsetzen. Der Kontaktlinsenträger sollte die Linse entsorgen und eine neue Linse aufsetzen**.**

Befindet sich Schmutz, eine Wimper oder ein Fremdkörper auf der Kontaktlinse und ein Fremdköpergefühl verschwindet nach dem Abnehmen der Kontaktlinse vom Auge, sollte der Kontaktlinsenträger die Kontaktlinse auch dann entsorgen, wenn sie unbeschädigt scheint. In der Folge, kann dann eine neue, frische Kontaktlinse aufgesetzt werden. Besteht das Problem nach dem Absetzen der Kontaktlinse weiterhin, soll der Kontaktlinsenträger KEINE neue Kontaktlinse mehr aufsetzen, sondern **UNVERZÜGLICH DEN KONTAKT-LINSENANPASSER AUFSUCHEN.**

Der Kontaktlinsenträger sollte auch dazu angewiesen werden, **KEINE** neue Kontaktlinse als Selbstbehandlung des Problems zu verwenden. Der Kontaktlinsenträger soll darüber informiert werden, dass bei Auftreten eines der oben genannten Symptome ernsthafte Beschwerden wie eine Infektion, ein Hornhautgeschwür, Neubildung von Gefäßen oder eine Entzündung der Regenbogenhaut vorliegen können. Der Kontaktlinsenträger soll angewiesen werden, das Problem sofort medizinisch untersuchen und behandeln zu lassen, um eine ernsthafte Schädigung der Augen zu vermeiden.

Bei therapeutischem Einsatz kann eine Nebenwirkung durch die ursprüngliche Krankheit oder Verletzung oder durch das Tragen von Kontaktlinsen auftreten. Es besteht die Möglichkeit der Verschlimmerung der bestehenden Krankheit/Beschwerden, wenn eine weiche Kontaktlinse zu therapeutischen Zwecken verwendet wird, um ein verletztes Auge, bei dem bereits Symptome vorliegen, zu behandeln. Der Patient sollte angewiesen werden,

den Kontaktlinsenanpasser SOFORT aufzusuchen, wenn sich die Symptome beim Tragen der Linsen verstärken, um eine ernsthafte Schädigung der Augen zu verhindern.

Anweisungen zur Pflege der Kontaktlinsen

Bei der Anpassung von Linsen sollte der Kontaktlinsenanpasser dem Kontaktlinsenträger geeignete, adäquate Warnungen und Anweisungen geben, die zum individuellen Kontaktlinsentyp und Tragemodus des Kontaktlinsenträgers passen. Der Kontaktlinsenanpasser sollte ein geeignetes Pflegesystem empfehlen, das auf die individuellen Anforderungen des Kontaktlinsenträgers abgestimmt ist.

Eine Nichteinhaltung der Anweisungen zur korrekten Pflege von Kontaktlinsen kann zu ernsthaften Augenschädigungen führen, wie im Abschnitt „**Warnungen**“ beschrieben.

Vollständige Informationen zur Verwendung, Pflege, Reinigung, Desinfektion und Aufbewahrung von Kontaktlinsen finden Sie in der Ratgeberbroschüre für ACUVUE® Kontaktlinsen .

Wenn ACUVUE® Kontaktlinsen zur Wiederverwendung gemäß **Tabelle 1** empfohlen werden, muss die Linse nach dem Abnehmen und vor dem Aufsetzen gereinigt und desinfiziert werden. Die Kontaktlinsen dürfen ausschließlich mit einem chemischen System desinfiziert werden (z. B. Mehrzweck- oder Wasserstoffperoxid-System).

Der Kontaktlinsenanpasser sollte mit dem Kontaktlinsenträger die Anweisungen zur Pflege der Kontaktlinsen (allgemeine Informationen, Reinigung der Kontaktlinsen) sowie die individuell für diesen Kontaktlinsenträger festgelegten Pflegeanweisungen besprechen. Da das Material mancher Kontaktlinsen Silikon enthält, wie in **Tabelle 1** dargestellt, kann die Benetzbarkeit variieren, wenn unterschiedliche Kontaktlinsen-Pflegemittel verwendet werden.

Vorgehensweise bei einer festsitzenden (nicht beweglichen) Kontaktlinse

Wenn die Kontaktlinse fest am Auge haftet, sich also nicht mehr bewegt, sollte der Kontaktlinsenträger einige Tropfen einer empfohlenen Benetzungs- oder Nachbenetzungslösung direkt auf das Auge geben und dann abwarten, bis die Kontaktlinse wieder frei auf dem Auge beweglich ist. Erst danach soll die Kontaktlinse vom Auge genommen werden. Wenn die Kontaktlinse auch nach einigen Minuten noch nicht wieder frei beweglich ist, sollte der Kontaktlinsenträger unverzüglich den Kontaktlinsenanpasser aufsuchen.

Vorgehensweise bei einer ausgetrockneten (dehydrierten) Kontaktlinse

Wenn eine ACUVUE® Kontaktlinsen für einen längeren Zeitraum vom Auge abgenommen wird, kann die Oberfläche austrocknen und nach und nach ihre Benetzbarkeit verlieren. Die Kontaktlinse ist in diesem Fall zu entsorgen und durch eine neue Kontaktlinse zu ersetzen.

NOTFÄLLE

Der Kontaktlinsenträger ist darüber zu informieren, dass beim Eindringen von Chemikalien jeglicher Art (Haushaltsreiniger, Flüssig-Gartendünger, Schädlingsbekämpfungsmittel, Laborchemikalien usw.) in das Auge wie folgt vorzugehen ist: **DIE AUGEN SOFORT MIT VIEL WASSER SPÜLEN UND UNVERZÜGLICH EINEN AUGENARZT ODER DIE AMBULANZ/NOTAUFNAHME EINER KLINIK AUFSUCHEN.**

MELDUNG VON NEBENWIRKUNGEN

Alle Fälle erheblicher Nebenwirkungen und Unverträglichkeiten, die beim Tragen oder im Zusammenhang mit den ACUVUE® Kontaktlinsen beobachtet werden, sind bei folgender Stelle zu melden:

Germany
Johnson & Johnson Medical GmbH
Robert-Koch-Straße 1, 22851 Norderstedt, Tel.: 0800/ 100 25 90, Fax: 01803/0 00 311

Austria
Johnson & Johnson Medical Products
Gunoldstr. 16, 1190 Wien, Tel.: 01/3 60 25-235, Fax: 01/3 60 25-516

Switzerland
Johnson & Johnson AG
Gubelstr. 34, 6300 Zug, Tel.: 0800/563992, Fax: 0800/82 00 82

Weitere Informationen

Um weitere Informationen zu ACUVUE® Kontaktlinsen zu erhalten oder Ihre kostenlose Ratgeberbroschüre zu ACUVUE® Kontaktlinsen zu bestellen, wenden Sie sich bitte unter der oben aufgeführten Adresse.

Hersteller:

Herstellungsort siehe Verpackung

USA:
Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville
Florida, 32256
USA

IRELAND:
Johnson & Johnson Vision Care (Ireland)
The National Technology Park
Limerick
Ireland

Bevollmächtigter in der EU:
Johnson & Johnson Medical Limited
Pinewood Campus
Nine Mile Ride
Wokingham
RG40 3EW
United Kingdom
www.acuvue.com

Nederlands

Belangrijk: lees deze informatie zorgvuldig door en bewaar deze voor toekomstig gebruik. Deze productbijlage is bedoeld voor de contactlensspecialist maar dient ook beschikbaar te worden gesteld aan lensdragers, als deze daarom vragen. Deze productbijlage bevat belangrijke informatie over het juiste gebruik van ACUVUE® contactlenzen die zijn vermeld in tabel 1. Tevens bevat deze productbijlage informatie over bijwerkingen en contra-indicaties.

Johnson & Johnson Medical BV levert bij ACUVUE® contactlenzen een instructieboekje met aanvullende informatie voor de dragers van de lenzen. De contactlensspecialist dient ervoor te zorgen dat de drager het instructieboekje ontvangt dat bij de aan hem of haar voorgeschreven contactlens hoort.

Tabel 1

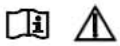
Lenstype en merknaam	Beoogd gebruik en draagschema			Binnenstebuiten Indicator	Materiaal	Polymeer-/water-gehalte (%)	Verpakkingsoplossing
	Dagelijks gebruik - Eenmalig	Dagelijks gebruik - Regelmatige	Langdurig gebruik				
ACUVUE® sferische contactlenzen - met tint en UV-filter							
ACUVUE®2® contactlenzen		⊙	⊙	123	etafilcon A	42/58	❶
1•DAY ACUVUE® contactlenzen	⊙			123	etafilcon A	42/58	❶
1•DAY ACUVUE® MOIST contactlenzen	⊙			123	etafilcon A	42/58	❸
ACUVUE® ADVANCE® contactlenzen met HYDRACLEAR®		⊙		123	galyfilcon A ❹	53/47	❷
ACUVUE OASYS® contactlenzen met HYDRACLEAR® PLUS		⊙	⊙	123	senofilcon A ❹	62/38	❷
ACUVUE OASYS® contactlenzen met HydraLuxe™	⊙			123	senofilcon A ❹	62/38	❷
1•DAY ACUVUE® TruEye® contactlenzen	⊙			123	narafilcon A ❹	54/46	❷
ACUVUE® ADVANCE® PLUS contactlenzen met HYDRACLEAR®		⊙		123	galyfilcon A ❹	53/47	❷
1•DAY ACUVUE® DEFINE® contactlenzen met LACREON®	⊙				etafilcon A	42/58	❸
ACUVUE® Vita™ contactlenzen		⊙		123	senofilcon C ❹	59/41	❷
ACUVUE® for ASTIGMATISM contactlenzen - met tint en UV-filter							
1•DAY ACUVUE® MOIST contactlenzen met ASTIGMATISM	⊙				etafilcon A	42/58	❸
1•DAY ACUVUE® for ASTIGMATISM contactlenzen	⊙				etafilcon A	42/58	❶
ACUVUE OASYS® contactlenzen for Astigmatism met HydraLuxe™	⊙				senofilcon A ❹	62/38	❷
ACUVUE® ADVANCE® for ASTIGMATISM contactlenzen met HYDRACLEAR®		⊙			galyfilcon A ❹	53/47	❷
ACUVUE OASYS® for ASTIGMATISM contactlenzen met HYDRACLEAR® PLUS		⊙	⊙		senofilcon A ❹	62/38	❷
ACUVUE® Vita™ contactlenzen for ASTIGMATISM		⊙			senofilcon C ❹	59/41	❷
ACUVUE® for PRESBYOPIA contactlenzen - met tint en UV-filter							
ACUVUE® BIFOCAL contactlenzen		⊙	⊙	123	etafilcon A	42/58	❶
ACUVUE OASYS® for PRESBYOPIA contactlenzen met HYDRACLEAR® PLUS		⊙	⊙		senofilcon A ❹	62/38	❷
1•DAY ACUVUE® MOIST contactlenzen MULTIFOCAL	⊙			123	etafilcon A	42/58	❸

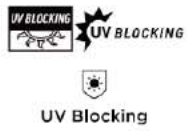
Verklaring

Oplossing voor de verpakking: ❶ Gebufferde zoutoplossing ❷ Gebufferde zoutoplossing met methylethercellulose ❸ Gebufferde zoutoplossing met povidone **Materiaal:** ❹ Lensmateriaal bevat silicone *en voldoen aan de Klasse 1* UV absorptie standaard, met een transmissie van minder dan 1% UVB (280-315 nm) en minder dan 10% UVA (316-380 nm) UV straling. Alle Etafilcon A prodcuten voldoen aan de Klasse 2 UV absorptie standaard, met een transmissie van minder dan 5% UVB en minder dan 50% UVA straling.

Betekenis van symbolen

Op het etiket of de verpakking van uw ACUVUE® contactlenzen kunnen de volgende symbolen voorkomen.

SYMBOOL	DEFINITIE
	Raadpleeg instructieboekje
	Gefabriceerd door of in
	Datum van de fabrikant
	Te gebruiken voor (houdbaarheidsdatum)
	Partijnummer
	Steriel door stoom of hete lucht
	Niet hergebruiken (voor eenmalig gebruik)
DIA	Diameter
BC	Basiskromming
D	Dioptrie (lenssterkte)
CYL	Cilindersterkte
AXIS	As
MAX ADD	Hoogste additie die kan worden gecorrigeerd
LOW	"Laag" near ADD (+0,75 tot +1,25 ADD)
	Geautoriseerde vertegenwoordiger voor de EU

SYMBOOL	DEFINITIE
MID	"Middel" near ADD (+1,50 tot +1,75 ADD)
HGH	"Hoog" near ADD (+2,00 tot +2,50 ADD)
S_H	NATURAL SHIMMER™
S_P	NATURAL SPARKLE™
N	NATURAL SHINE™
	Kwaliteitswaarborg
 UV Blocking	UV-filter
	Verwijderingsbijdrage
	LET OP: federale wetten in de V.S. bepalen dat dit product uitsluitend mag worden verkocht door of op verzoek van een officiële contactlensspecialist
	Juiste plaatsing lens
	Onjuiste plaatsing lens (binnenstebuiten)
	Aanduiding voor houders en verpakkingen van papier
	Aanduiding voor samengestelde materialen

INHOUD

ACUVUE® contactlenzen worden geleverd in afzonderlijke steriele blisterverpakkingen, waarbij de lens is ingelegd in een gebufferde zoutoplossing (zie **tabel 1** bij Verpakkingsoplossing). **NIET GEBRUIKEN** als de steriele verpakking geopend of beschadigd is.

GEBRUIKSBESTEMMING

ACUVUE® sferische contactlenzen

Deze zijn geschikt voor dagelijks gebruik of langdurig gebruik, zoals aangegeven in **tabel 1**, voor de optische correctie van refractieve ametropie (myopie en hyperopie) bij personen met en zonder natuurlijke lens (afakie) en verder gezonde ogen, met een astigmatisme van 1,00D of minder.

1•DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON® zijn ook bedoeld om het oog te verfraaien of te veranderen.

ACUVUE® Brand Contact Lenses for Astigmatism

Deze zijn geschikt voor dagelijks gebruik of langdurig gebruik, zoals aangegeven in **tabel 1**, voor de optische correctie van refractieve ametropie (myopie en hyperopie) bij personen met en zonder natuurlijke lens (afakie) en verder gezonde ogen, met een astigmatisme.

ACUVUE® Brand Contact Lenses for Presbyopia

Deze zijn geschikt voor dagelijks gebruik of langdurig gebruik, zoals aangegeven in **tabel 1**, voor de optische correctie van refractieve ametropie (myopie en hyperopie) bij personen met presbyopie, met en zonder natuurlijke lens (afakie) en verder gezonde ogen, met een astigmatisme van 0,75D of minder.

Daarnaast kunnen ACUVUE OASYS® contactlenzen met HYDRACLEAR® PLUS worden voorgeschreven voor therapeutisch gebruik als bandagelens in geval van de volgende acute en chronische oogaandoeningen:

- Voor bescherming van het hoornvlies bij aandoeningen van het ooglid en het hoornvlies, zoals entropion, trichiasis, tarsale littekens en recidiverende hoornvlieserosie. Bovendien kunnen deze contactlenzen worden voorgeschreven ter bescherming in geval van hechtingen of vervorming, aantasting of verlamming van de oogstructuur om het hoornvlies te beschermen tegen blootstelling of herhaalde irritatie.

- Voor verlichting van pijn aan het hoornvlies, bijvoorbeeld in geval van bulleuze keratopathie, epitheliale erosie en abrasie, filamentaire keratitis, en na keratoplastiek.
- Voor gebruik als een barrière tijdens het genezingsproces van epitheliale aandoeningen, zoals chronische epitheliale aandoeningen, corneale ulcer, neurotrofe en neuroparalytische keratitis, en chemische brandwonden.
- Voor gebruik na operaties wanneer het gebruik van een bandagelens wordt voorgeschreven, zoals post-refractieve chirurgie, lamellaire transplantaties, corneale flappen en andere oogchirurgische omstandigheden.
- Voor structurele stabiliteit en bescherming bij het piggy-back lenssysteem dat wordt toegepast wanneer het hoornvlies en aangrenzende oppervlakken te onregelmatig zijn om gangbare harde vormstabiele (RGP) lenzen te kunnen aanmeten. Gebruik van de lens voorkomt bovendien irritatie en pijnlijke ogen bij littekenweefsel of andere onregelmatigheden op het oogoppervlak.

ACUVUE OASYS® contactlenzen met HYDRACLEAR® PLUS die worden voorgeschreven voor therapeutisch gebruik, kunnen worden gedragen op basis van dagelijks gebruik of langdurig gebruik.

Alle ACUVUE® contactlenzen zijn voorzien van een UV-filter om de cornea te helpen bij het beschermen de schadelijke gevolgen van UV-straling.

WAARSCHUWING: UV-absorberende contactlenzen zijn GEEN vervanging voor beschermende UV-absorberende brillen, zoals een UV-absorberende ski- of zonnebril, aangezien ze het oog en het gebied eromheen niet volledig bedekken. U moet UV-absorberende brillen blijven dragen zoals aangegeven.

Opmerking: langdurige blootstelling aan UV-straling is een van de risicofactoren voor het ontstaan van staar (cataract). Het blootstellingsniveau is afhankelijk van een aantal factoren, zoals omgevingsfactoren (hoogte, geografische locatie, bewolking) en persoonlijke factoren (soort en duur van activiteiten in de buitenlucht). Alle ACUVUE® contactlenzen zijn voorzien van een UV-filter dat de cornea en het oog helpt beschermen tegen de schadelijke gevolgen van UV-straling. Tot dusverre zijn er echter geen klinische onderzoeken uitgevoerd die aantonen dat het dragen van contactlenzen met UV-filter het risico op het ontstaan van cataract of andere oogziekten vermindert. Raadpleeg voor meer informatie uw contactlensspecialist.

DRAAGSCHEMA

Het draag- en vervangschema dienen te worden vastgesteld door de contactlensspecialist. Lensdragers zijn vooral in het begin geneigd de lenzen te lang te dragen. De contactlensspecialist dient te wijzen op het belang van het volgen van het maximum

draagschema voor de beginperiode. Daarnaast zijn regelmatige controles, zoals voorgeschreven door de contactlensspecialist, buitengewoon belangrijk.

Dagelijks gebruik (Eenmalig gebruik)

ACUVUE® contactlenzen, voorgeschreven voor Dagelijks gebruik - Eenmalig gebruik (voor minder dan 24 uur gebruik, niet tijdens het slapen) zoals aangegeven in **tabel 1**, zijn bedoeld als daglenzen voor eenmalig gebruik en moeten na het uitnemen worden weggegooid. **Desinfectie of reiniging van de lenzen is in dit geval overbodig.**

1.DAY ACUVUE® TruEye® Brand contactlenzen zijn niet ontwikkeld voor gebruik in combinatie met contactlens reinigers of desinfectiesystemen. De lenzen dienen te worden weggegooid na gebruik. Start elke draagperiode met een frisse nieuwe contactlens.

Dagelijks gebruik - Regelmatige vervanging

Alle ACUVUE® Vita™ contactlenzen voor Dagelijks gebruik - Regelmatige vervanging (voor minder dan 24 uur gebruik, niet tijdens het slapen) zoals aangegeven in **tabel 1**, moeten elke maand door nieuwe lenzen worden vervangen.

Alle anders ACUVUE® contactlenzen voor Dagelijks gebruik - Regelmatige vervanging moeten elke twee weken door nieuwe lenzen worden vervangen.

Alle ACUVUE® contactlenzen die in **tabel 1** onder de kop Dagelijks gebruik - Regelmatige vervanging zijn vermeld, moeten telkens na het uitnemen worden gereinigd, afgespoeld en gedesinfecteerd, waarbij uitsluitend een chemisch desinfectiesysteem mag worden gebruikt.

Langdurig gebruik

ACUVUE® contactlenzen voor Langdurig gebruik (voor minder dan 24 uur gebruik, ook tijdens het slapen) zoals aangegeven in **tabel 1**, zijn bedoeld voor aaneengesloten gebruik tot maximaal 7 dagen/6 nachten en moeten na het uitnemen worden weggegooid. Deze gebruikswijze maakt **reinigen of desinfecteren overbodig**.

Het is raadzaam om bij nieuwe contactlensdragers eerst te bekijken hoe ze op een schema van Dagelijks gebruik - Regelmatige vervanging van contactlenzen reageren. Als de contactlensspecialist van mening is dat de klant een geschikte kandidaat is voor langdurig gebruik, wordt de specialist aangeraden om op basis van de respons van de klant een draagschema op te stellen.

Na het uitnemen van de contactlenzen wordt aanbevolen om deze gedurende de periode van nachtrust of langer uit het oog te laten. Gedurende de beginperiode van langdurig gebruik dient de contactlensspecialist de drager regelmatig te onderzoeken.

CONTRA-INDICATIES

GEBRUIK GEEN ACUVUE® contactlenzen als één van de volgende situaties van toepassing is wanneer u contactlenzen voorschrijft voor correctie van refractieve ametropie.

- Acute of subacute ontsteking of infectie van de voorste oogkamer.
- Elke oogaandoening, beschadiging of afwijking van de cornea, de conjunctiva of de oogleden.
- Ernstige lacrimale secretie-insufficiëntie (droge ogen).
- Corneale hypesthesie (verminderde corneale gevoeligheid).
- Elke systemische aandoening die invloed kan hebben op de ogen of door het dragen van contactlenzen kan verergeren.
- Allergische reacties van het oogoppervlak of aanhangsels, die kunnen worden veroorzaakt of verergerd door het dragen van contactlenzen of het gebruik van lensvloeistof.
- Allergie voor een ingrediënt, zoals kwik of Thimerosal, in een oplossing die is bedoeld voor het onderhoud van lenzen voor regelmatig gebruik.
- Een actieve corneale infectie (bacterie, schimmel, **protozoön** of virus).
- Rode of geïrriteerde ogen.

Voor THERAPEUTISCH GEBRUIK kan de contactlensspecialist ACUVUE OASYS® contactlenzen met HYDRACLEAR® PLUS voorschrijven als hulp bij het genezingsproces van bepaalde oogaandoeningen, waartoe bovengenoemde aandoeningen kunnen behoren.

WAARSCHUWINGEN

(Dagelijks gebruik = contactlens voor minder dan 24 uur gebruik, terwijl wakker; Langdurig gebruik = contactlens voor meer dan 24 uur gebruik, ook tijdens slaap). Een juist en zorgvuldig gebruik van contactlenzen en lensverzorgingsproducten, met inbegrip van lenshouders, is essentieel voor een veilig gebruik. Problemen voortkomend uit het dragen van contactlenzen of het gebruik van producten voor het onderhoud van contactlenzen kunnen ernstige schade aan de ogen veroorzaken.

Dragers moeten op de hoogte worden gebracht van de volgende waarschuwingen met betrekking tot het dragen van contactlenzen:

- ACUVUE® daglenzen worden voorgeschreven voor het dragen overdag en voor eenmalig gebruik. Studies hebben aangetoond dat het dragen zachte daglenzen het risico verminderd op het krijgen van sommige complicaties waaronder discomfort en ontstekingen die zijn gerelateerd aan het verzorgen en hanteren van lenzen, en dat het hergebruik van lenzen een groter risico vormt op het krijgen van voorgenoemde problemen.

- Problemen met contactlenzen of producten voor het onderhoud van contactlenzen kunnen ernstige schade aan de ogen veroorzaken. Dragers moeten erop worden gewezen dat het voor een veilig gebruik van contactlenzen en producten voor het onderhoud daarvan, inclusief lenshouders, essentieel is om deze producten op de juiste manier te gebruiken en te verzorgen. †
- Oogproblemen, met inbegrip van corneale ulcers, kunnen zich in rap tempo ontwikkelen en kunnen leiden tot vermindering van de visus.
- Uit onderzoeksresultaten blijkt dat het risico op ulceratieve keratitis groter is bij EW-dragers dan bij DW-dragers.
- Bij DW-dragers die hun lenzen 's nachts inhouden (en daarmee afwijken van de goedgekeurde indicatie), is het risico op ulceratieve keratitis groter dan bij dragers die de lenzen niet 's nachts inhouden.
- Het risico op ulceratieve keratitis kan in het algemeen worden verminderd door de richtlijnen voor het verzorgen van de lenzen nauwkeurig te volgen, met inbegrip van het schoonmaken van de lenshouder.
- Uit onderzoeksresultaten blijkt dat het risico op ulceratieve keratitis groter is bij dragers die roken dan bij niet-rokers.
- Stel uw lenzen niet bloot aan contact met water tijdens zwemmen, andere watersporten of het nemen van een bad omdat dit het risico vergroot op het krijgen van een serieuze ooginfectie door micro-organismen wat kan leiden tot het verlies van het gezichtsvermogen. Als lenzen in contact zijn geweest met water, dient de gebruiker deze weg te gooien en te vervangen door een nieuw paar lenzen. U dient uw oogzorg professional te raadplegen voor adviezen over het gebruik van lenzen tijdens activiteiten met water.

Als de ogen van de drager pijnlijk aanvoelen, meer dan normaal tanen of rood zijn, als het gezichtsvermogen vermindert of zich andere problemen voordoen, moeten de contactlenzen onmiddellijk uitgenomen worden en moet de drager direct contact opnemen met zijn of haar contactlensspecialist. Contactlensdragers worden aangeraden regelmatig een bezoek brengen aan hun contactlensspecialist, zoals voorgeschreven is door de contactlensspecialist.

† Bron: New England Journal of Medicine, 21 September 1989, 321 (12), pp. 773-783

VOORZORGSMAATREGELEN

Wat te doen bij problemen

ADVISEER DE DRAGER OM DE CONTACTLENZEN ONMIDDELLIJK UIT TE NEMEN EN CONTACT OP TE NEMEN MET DE CONTACTLENSSPECIALIST VOOR ADVIES.

Speciale voorzorgsmaatregelen voor de contactlensspecialist

Vanwege het kleine aantal deelnemers aan klinische onderzoeken naar lenzen, worden de beschikbare refractie waarden, de ontwerpconfiguraties of de lensparameters van het lensmateriaal niet geëvalueerd bij een statistisch significant aantal deelnemers. Contactlensspecialisten moeten daarom bij de keuze van een passend lensontwerp en lensparameters alle kernmerken van de lens in aanmerking nemen die van invloed kunnen zijn op de lensprestaties en de oculaire gezondheid, inclusief zuurstoftransmissie, bevochtigingsmogelijkheden, centrale en perifere dikte en diameter van de optische zone.

De mogelijke invloed van deze factoren op de oculaire gezondheid van de drager moet zorgvuldig worden afgewogen tegen de noodzaak van refractieve correctie; om die reden moet de voorschrijvende contactlensspecialist de oculaire gezondheid van de drager en de lensprestaties voor het oog het nauwlettend in de gaten houden.

- Vanwege de verminderde lichtdoorlatendheid van gekleurde lenzen kunnen sommige dragers van *1•DAY* ACUVUE® DEFINE® Brand Contact Lenses with LACREON® visuele symptomen ervaren. Daarnaast kan bij sommige dragers door het ondoorzichtige irispatroon een bewustzijn van de periferie van de lens optreden.
- Voor dragers van de ACUVUE® contactlenzen voor correctie van presbyopie met monovision of multifocal zal de optische correctie van verziendheid of bijziendheid wellicht niet optimaal zijn. De wensen ten aanzien van scherp zicht zijn voor elke drager anders en de contactlensspecialist moet daarmee rekening houden bij de keuze van een passend type lens.
- Fluoresceïne, een gele kleurstof, mag niet worden gebruikt zolang de contactlenzen nog op het oog zitten. De contactlenzen nemen deze kleurstof op en verkleuren daardoor. Als fluoresceïne in de ogen wordt gebruikt, moeten de ogen worden gespoeld met een steriele zoutoplossing die aanbevolen wordt voor gebruik in de ogen.
- De contactlensspecialist moet de drager nadrukkelijk wijzen op de noodzaak de lenzen bij rode of geïrriteerde ogen onmiddellijk te verwijderen.
- De contactlensspecialist moet de drager ook informeren over het onderhoudschema en de veiligheidsvereisten.

Voorzorgsmaatregelen voor gebruik

- Voordat de drager de praktijk van de contactlensspecialist verlaat, moet hij of zij in staat zijn om contactlenzen in te zetten en gemakkelijk uit te nemen of moet er iemand anders zijn die de contactlenzen voor hem of haar kan uitnemen.
- **NIET GEBRUIKEN** als de steriele verpakking geopend of beschadigd is.

- Was en spoel altijd uw handen voordat u contactlenzen aanraakt. Zorg dat de ogen of lenzen niet in contact komen met cosmetica, lotions, zeep, crèmes, deodorants of sprays. De lenzen kunnen het beste worden ingebracht voordat make-up wordt gebruikt.
- Raak de contactlenzen niet met de vingers of handen aan als de handen niet helemaal schoon zijn, omdat daardoor microscopisch kleine krassen op de lenzen kunnen ontstaan wat zichtstoornissen en/of beschadigingen van het oog kan veroorzaken.
- Houd nauwgezet de instructies voor gebruik, inbrengen, uitnemen, schoonmaken, desinfecteren, opbergen en dragen van de lenzen aan zoals beschreven in het instructieboekje bij ACUVUE® contactlenzen en de lenzen die worden voorgeschreven door de contactlensspecialist.
- Behandel de lenzen met zorg en laat ze niet vallen.
- Gebruik geen pincet of ander hulpmiddel om de lenzen uit de lenshouder te halen, tenzij u speciaal voor dat doel een hulpmiddel hebt gekregen. Haal de lens voorzichtig uit de lenshouder door deze langs de wand van de lenshouder te laten glijden.
- Raak de lens niet aan met de vingernagels.
- Alle ACUVUE OASYS® contactlenzen met HYDRACLEAR® PLUS voor therapeutisch gebruik moeten onder supervisie worden gebruikt. Gebruik van geneesmiddelen voor de ogen moet tijdens behandeling met een bandagelens nauwgezet worden gevolgd door de contactlensspecialist. Bij sommige oogaandoeningen zal de contactlensspecialist de lenzen in- en uitnemen. In deze gevallen moet de contactlensspecialist de drager verzoeken de contactlenzen niet zelf in te brengen.

Voorzorgsmaatregelen voor het dragen

- Als de lens aan het oog plakt (niet beweegt), volgt u de richtlijnen in "Het verzorgen van een plakkende (niet-bewegende) lens". De lens moet vrij op het oog kunnen bewegen om de gezondheid van de ogen op termijn te waarborgen. Als de contactlens blijft plakken, moet de drager het advies krijgen onmiddellijk contact op te nemen met de contactlensspecialist.
- Draag de lenzen niet langer dan aanbevolen door de contactlensspecialist.
- Wanneer u spuitbussen met bijvoorbeeld haarlak gebruikt terwijl u lenzen in hebt, moet u dat voorzichtig doen en de ogen gesloten houden totdat alle spray is neergedaald.
- Vermijd schadelijke of irriterende dampen en rook wanneer u lenzen draagt.
- Laat andere mensen uw lenzen niet dragen. Het delen van contactlenzen vergroot de kans op een ooginfectie enorm.
- .Gooi na het verstrijken van aanbevolen draagperiode de gedragen lenzen altijd weg volgens de aanwijzingen van de contactlensspecialist.

Voorzorgsmaatregelen voor de contactlensvloeistof

- Verschillende contactlensvloeistoffen kunnen niet altijd samen worden gebruikt en niet alle vloeistoffen zijn veilig voor alle lenzen. Gebruik alleen de aanbevolen vloeistoffen.
- De drager moet niet van contactlensvloeistof veranderen zonder overleg met zijn of haar contactlensspecialist.
- Gebruik geen vloeistoffen die zijn aanbevolen voor vormstabiele lenzen (RGP-lenzen).
- Gebruik alleen contactlensvloeistof en lenzen waarvan de uiterste houdbaarheidsdatum nog niet is verstreken.
- Volg voor instructies voor gebruik van contactlensvloeistoffen altijd de aanwijzingen in de productbijlage.
- Gebruik voor de lenzen uitsluitend een chemisch desinfectiesysteem (geen hitte). Gebruik van een hittedesinfectiesysteem (thermale desinfectie) kan de ACUVUE® contactlenzen beschadigen.
- Niet-geconserveerde, steriele oplossingen moeten na gebruik op de aangegeven tijd worden weggegooid.
- Gebruik geen speeksel of iets anders dan de aanbevolen vloeistoffen voor het bevochtigen van de contactlenzen.
- Houd de lenzen volledig ondergedompeld in de aanbevolen opslagoplossing als de lenzen niet worden gedragen. Langere perioden van blootstelling aan lucht verkleinen de kans dat het oppervlak van de lens weer vochtig wordt. Volg de aanwijzingen in "Het verzorgen van een uitgedroogde (gedehydrateerde) lens" als het oppervlak van de lenzen droog wordt.

Voorzorgsmaatregelen voor de lenshouder

Contactlenshouders kunnen een bron van bacteriën zijn en moeten op de juiste wijze worden gebruikt en regelmatig worden gereinigd en vervangen volgens de aanwijzingen van de lenshouderfabrikant of de contactlensspecialist.

Andere zaken die dragers moeten weten

- Vraag uw contactlensspecialist ook om advies voordat u geneesmiddelen of oogdruppels gebruikt in uw ogen.
- Sommige medicijnen, zoals antihistaminica, decongestiva, diuretica, spierverslappers, kalmerende middelen en medicijnen tegen zee-, lucht- of wagenziekte, kunnen droge ogen veroorzaken, de lenzen meer voelbaar maken of het zicht vertroebelen. Als zich dergelijke omstandigheden voordoen, moeten er passende maatregelen worden genomen.

- Gebruikers van de anticonceptiepil kunnen bij het gebruik van contactlenzen veranderingen ondervinden in hun zicht of in de mate waarin zij contactlenzen kunnen verdragen. Dragers moeten hierover worden ingelicht.
- Voor alle contactlenzen geldt dat vervolgbezoeken aan de contactlensspecialist de gezondheid van het oog op termijn waarborgen. De contactlensspecialist moet een de drager verzoeken zich te houden aan gemaakte vervolgafspraken.

Wie moet weten dat u contactlenzen draagt?

- Breng all uw artsen (behandelaars) op de hoogte van het feit dat u contactlenzen draagt.
- Breng ook de werkgever altijd op de hoogte van het feit dat u contactlenzen draagt. Bij sommige werkzaamheden kan oogbescherming vereist zijn of is het dragen van contactlenzen wellicht niet toegestaan.

BIJWERKINGEN

De drager moet op de hoogte worden gebracht van het feit dat de volgende problemen kunnen optreden tijdens het dragen van ACUVUE® contactlenzen:

- De ogen kunnen branden, prikken of jeuken.
- De lenzen kunnen na verloop van tijd minder comfortabel aanvoelen.
- De drager kan het gevoel krijgen dat er iets in het oog zit (stofje, krasje).
- Er kunnen tijdelijke verslechteringen ontstaan vanwege perifere infiltraten, perifere corneale ulceratie en cornea-erosie. Ook kunnen andere fysiologische indicaties worden waargenomen, zoals lokaal of algemeen oedeem, corneale neovascularisatie, corneale staining, vaatingroei, tarsale afwijkingen, iritis en conjunctivitis. Sommige hiervan zijn in beperkte mate klinisch aanvaardbaar.
- De ogen kunnen meer tranen dan normaal, een ongebruikelijke afscheiding vertonen of de ogen kunnen rood worden.
- Onscherp zicht, wazig zicht, halo's of bogen rondom voorwerpen, fotofobie of symptomen van droge ogen kunnen zich eveneens voordoen bij aaneengesloten of te lang gebruik van de contactlenzen.

De contactlensspecialist moet de drager adviseren dagelijks een simpele, driedelige zelftest uit te voeren. Hierbij beantwoordt de drager de volgende drie vragen:
- Hoe voelen de lenzen aan?
- Hoe zien mijn ogen eruit?
- Merk ik een verschil in mijn gezichtsvermogen?

Als de drager een probleem ervaart, moet hij of zij de **CONTACTLENZEN ONMIDDELLIJK UITNEMEN**. Zodra het ongemak of probleem stopt, moet de drager de lenzen onderzoeken.

Wanneer de lenzen op enige manier zijn beschadigd, mag de drager de lenzen **NIET** opnieuw inbrengen. Hij of zij moet de lenzen weggooien en vervangen door een nieuwe.

Als op de contactlens een stofje of een wimper is achtergebleven, of als het probleem stopt en de lens onbeschadigd lijkt, moet de drager het advies krijgen de lens weg te

gooien en te vervangen door een nieuwe. Als het probleem zich opnieuw voordoet, mag de drager de lens **NIET** meer inbrengen en moet hij of zij **ONMIDDELLIJK CONTACT OPNEMEN MET DE CONTACTLENSSPECIALIST**.

Adviseer de drager ook om **NIET** een nieuwe lens te gebruiken om het probleem zelf te verhelpen. Wijs de drager er op dat de bovenstaande symptomen kunnen wijzen op een ernstige aandoening, zoals infectie, corneale ulcer, neovascularisatie of iritis. Raad de drager aan om zo snel mogelijk medische hulp en snelle behandeling te zoeken voor het probleem om ernstige oogbeschadigingen te voorkomen.

Bij therapeutisch gebruik van de contactlenzen kunnen zich bijwerkingen voordoen die een gevolg kunnen zijn van ofwel de behandelde aandoening of verwonding, of van het dragen van de contactlenzen. Het is mogelijk dat een bestaande aandoening of conditie verergert wanneer een zachte contactlens wordt gebruikt voor de behandeling van een aangedaan oog. Raad de drager aan om **ONMIDDELLIJK** contact op te nemen met de contactlensspecialist wanneer de symptomen tijdens het dragen van lenzen verergeren om ernstige oogbeschadigingen te voorkomen.

Richtlijnen voor lensverzorging

De contactlensspecialist dient bij het verstrekken van contactlenzen de drager alle waarschuwingen en instructies voor het desbetreffende lenstype en draagschema mee te delen. De contactlensspecialist dient een systeem aan te bevelen dat geschikt is voor de individuele vereisten van de drager.

Het niet navolgen van de juiste renigingsprocedure kan leiden tot ernstig oogletsel, zoals beschreven in het gedeelte "**Waarschuwingen**". Voor volledige informatie over gebruik, verzorging, schoonmaak, desinfectie en bewaren van de ACUVUE® contactlenzen kunt u het instructieboekje voor lensdragers raadplegen.

ACUVUE® contactlenzen die in **tabel 1** onder de kop Dagelijks gebruik - Regelmatige vervanging zijn vermeld, moeten telkens na het uitnemen en vóór hergebruik worden gereinigd en gedesinfecteerd. Voor de desinfectering van de lenzen mag uitsluitend een chemisch desinfectiesysteem worden gebruikt (bijvoorbeeld een alles-in-één vloeistof of waterstofperoxideoplossing).

Neem de richtlijnen voor contactlensverzorging door met de drager, inclusief de basisinformatie over contactlensverzorging en het reinigen van de lenshouder, en de specifieke instructies met betrekking tot het schema voor contactlensverzorging dat u de drager hebt voorgeschreven. Aangezien bepaald lensmateriaal silicone bevat, zoals in **tabel 1** is aangegeven, kan de bevochtigbaarheid variëren bij het gebruik van verschillende producten voor het onderhoud van contactlenzen.

Het verzorgen van een plakkende (niet-bewegende) lens

Als de contactlens gaat plakken (niet meer beweegt), moet de drager een paar druppels van de aanbevolen bevochtigende vloeistof rechtstreeks op het oog aanbrengen en vervolgens wachten totdat de contactlens vrij op het oog begint te bewegen alvorens deze uit te nemen. Als de contactlens na een paar minuten nog steeds niet beweegt, moet de drager onmiddellijk contact opnemen met de contactlensspecialist.

Het verzorgen van een uitgedroogde (gedehydrateerde) lens

Als een ACUVUE® contactlens zich gedurende lagere tijd buiten het oog bevindt, kan het lensoppervlak droog worden en geen vocht meer opnemen. Vervang de contactlens in dat geval door een nieuwe.

NOODGEVALLEN

De drager moet worden verteld wat te doen als er een willekeurig chemisch product (schoonmaakproducten, onkruidverdelgers, chemische stoffen, enzovoort) in de ogen terechtkomt: **DE OGEN ONMIDDELLIJK SPOELEN MET KRAANWATER EN ONMIDDELLIJK CONTACT OPNEMEN MET DE CONTACTLENSSPECIALIST OF NAAR DE AFDELING SPOEDEISENDE HULP VAN EEN ZIEKENHUIS GAAN ZONDER UITSTEL.**

BIJWERKINGEN MELDEN

Alle ernstige afwijkende reacties en bijwerkingen die worden waargenomen bij dragers van ACUVUE® contactlenzen of die worden waargenomen tijdens het gebruik van de lenzen, dienen te worden gemeld aan:

Johnson & Johnson Medical BV,
Computerweg 14, 3800 AD Amersfoort
Tel: +31 (0)33 4500500
Fax: +31 (0)33 4500505

Aanvullende informatie

Voor meer informatie over ACUVUE® contactlenzen of bestellingen van gratis instructieboekjes voor lensdragers kunt u contact opnemen met de op het bovenvermelde adres.

Fabrikant:

Raadpleeg de verpakking voor plaats van fabricage

USA:
Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville
Florida, 32256
USA

IRELAND:
Johnson & Johnson Vision Care (Ireland)
The National Technology Park
Limerick
Ireland

Geautoriseerde vertegenwoordiger voor de EU:
Johnson & Johnson Medical Limited
Pinewood Campus
Nine Mile Ride
Wokingham
RG40 3EW
United Kingdom
www.acuvue.com

Türkçe

Önemli: Lütfen dikkatle okuyun ve daha sonra kullanmak üzere bu bilgileri saklayın. Bu Prospektüs Göz Hastalıkları Uzmanına yöneliktir ancak talep edilmesi durumunda hastalara da verilebilir. Bu prospektüs, Tablo 1'de sıralanan ACUVUE® Brand Contact Lenses ürünlerinin doğru kullanımı ile yan etkiler ve kontraendikasyonlarla ilgili önemli bilgiler içerir.

Johnson & Johnson Sıhhi Malzeme San. ve Tic. Ltd. Şti., kontakt lens kullanımıyla ilgili ayrıntılı bilgiler içeren ACUVUE® Brand Contact Lenses Hasta Talimat Kılavuzlarını sunmaktadır. Göz Hastalıkları Uzmanı, hastaya reçete edilen lense ait Hasta Talimat Kılavuzunu hastaya vermelidir.

Tablo 1

Lens türü ve Marka adı	Amaçlanan Kullanım ve Kullanım Programı			iç –dış göstergesi	Materyal	Polimer/su içeriği (%)	Ambalaj Solüsyonu
	Günlük Kullanım - GünBoyunca Kullan ve At	Günlük Kullanım-Sık değiştirme	Uzun Süreli Kullanım				
ACUVUE® Marka Sferik Kontakt Lensler - UV Blokajlı Görünürlük Rengi							
ACUVUE®2® Marka Kontakt Lensler		⊙	⊙	123	etafilcon A	42/58	❶
1•DAY ACUVUE® Marka Kontakt Lensler	⊙			123	etafilcon A	42/58	❶
1•DAY ACUVUE® MOIST Marka Kontakt Lensler	⊙			123	etafilcon A	42/58	❸
ACUVUE® ADVANCE® Marka HYDRACLEAR® içeren Kontakt Lensler		⊙		123	galyfilcon A ❹	53/47	❷
ACUVUE OASYS® Marka HYDRACLEAR® PLUS içeren Kontakt Lensler		⊙	⊙	123	senofilcon A ❹	62/38	❷
ACUVUE OASYS® Marka HydraLuxe™ içeren Kontakt Lensler	⊙			123	senofilcon A ❹	62/38	❷
1•DAY ACUVUE® TruEye® Marka Kontakt Lensler	⊙			123	narafilcon A ❹	54/46	❷
ACUVUE® ADVANCE® PLUS Marka HYDRACLEAR® içeren Kontakt Lensler		⊙		123	galyfilcon A ❹	53/47	❷
1•DAY ACUVUE® DEFINE® Marka LACREON® içeren Kontakt Lensler	⊙				etafilcon A	42/58	❸
ACUVUE® Vita™ Marka Kontakt Lensler		⊙		123	senofilcon C ❹	59/41	❷
ACUVUE® Marka ASTIGMATIZM için Kontakt Lensler - UV Blokajlı Görünürlük Rengi							
1•DAY ACUVUE® MOIST for ASTIGMATISM Marka Kontakt Lensler	⊙				etafilcon A	42/58	❸
1•DAY ACUVUE® for ASTIGMATISM Marka Kontakt Lensler	⊙				etafilcon A	42/58	❶
ACUVUE OASYS® for ASTIGMATISM Marka HydraLuxe™ içeren Kontakt Lensler	⊙				senofilcon A ❹	62/38	❷
ACUVUE® ADVANCE® for ASTIGMATISM Marka HYDRACLEAR® içeren Kontakt Lensler		⊙			galyfilcon A ❹	53/47	❷
ACUVUE OASYS® for ASTIGMATISM Marka HYDRACLEAR® PLUS içeren Kontakt Lensler		⊙	⊙		senofilcon A ❹	62/38	❷
ACUVUE® Vita™ for ASTIGMATISM Marka Kontakt Lensler		⊙			senofilcon C ❹	59/41	❷
ACUVUE® Marka PRESBIYOPI için Kontakt Lensler - UV Blokajlı Görünürlük Rengi							
ACUVUE® BIFOCAL Marka Kontakt Lensler		⊙	⊙	123	etafilcon A	42/58	❶
ACUVUE OASYS® for PRESBYOPIA Marka HYDRACLEAR® PLUS içeren Kontakt Lensler		⊙	⊙		senofilcon A ❹	62/38	❷
1•DAY ACUVUE® MOIST Marka Multifokal Kontakt Lensler	⊙			123	etafilcon A	42/58	❸

Tablo Anahtarı:

Ambalaj Solüsyonu: ❶ Tamponlanmış salin ❷ Metil eter selülozlu tamponlanmış salin ❸ Povidon ile tamponlanmış salin
Malzeme içeriği: ❹ Lens malzemesi silikon içerir ve 1. Sınıf UV emici satandartı ile UVB (280-315 nm) nin lensten geçebilme oranı %1 den ve UVA (316-380) nın %10 dan daha azdır. Tüm etafilcon A ürünleri 2. Sınıf UV emilimini UVB yi %5 den daha az, UVA yı % 50 daha az oranda geçirgenliği ile ile ağlar.

Sembol Anahtarı

Aşağıdaki semboller, ACUVUE® Brand Contact Lenses ürünlerinin etiket veya kutusunda bulunabilir.

SEMBOL	AÇIKLAMA
	Talimat Prospektüsüne Bakın
	Üretici (üretim yeri)
	Üretim tarihi
	Son Kullanma Tarihi
	Parti Kodu
	Buhar veya Kuru Isı Kullanılarak Sterilize Edilmiştir
	Tekrar Kullanmayın (Tek Kullanımlık)
DIA	Çap
BC	Temel Eğri
D	Dioptri (lens gücü)
CYL	Silindirik Güç
AXIS	Eksen
MAX ADD	Düzeltilebilir en yüksek yakın adisyon
LOW	" Düşük " yakın ADD (+0.75 den +1.25 e kadar ADD)
	AB Yetkili Temsilcisi

SEMBOL	AÇIKLAMA
MID	"Orta " yakın ADD (+1.50 to +1.75 ADD)
HGH	'Yüksek ' yakın ADD (+2.00 dan +2.50 ye kadar ADD)
S_H	NATURAL SHIMMER™
S_P	NATURAL SPARKLE™
N	NATURAL SHINE™
	Kalite Sistemi Onay Sembolü
  UV Blocking	UV Koruması İçerir
	Atık Yönetimi İçin Harç Ödenmiş
	DİKKAT: ABD Federal kanunları bu cihazın satışını yetkili bir doktor tarafından veya yetkili bir doktorun izniyle yapılacak şekilde sınırlandırmıştır.
	Lens Doğru Konumda
	Lens Doğru Konumda Değil (ters konumda)
	Kağıt kutular ve paketleme malzemeleri için ' tanımlayıcı işareti '
	Kompozit malzemeler için 'tanımlayıcı işareti'

İÇERİK

ACUVUE® Brand Contact Lenses ürünleri, lensler tamponlanmış salin solüsyon içinde olacak şekilde ayrı steril ambalajlar içinde temin edilir (Ambalaj Solüsyonları için bkz. **Tablo 1**). Steril blister ambalaj açılmışsa veya hasar görmüşse **KULLANMAYIN**.

KULLANIM AMACI

ACUVUE® Spherical Brand Contact Lenses

Bu ürünler, **Tablo 1**'de gösterildiği gibi Günlük Kullanım ve Uzun Süreli Kullanım için tasarlanmış olup gözlerinde hastalık bulunmayan ve 1.00D veya altında astigmatizm bulunan, afakik veya afakik olmayan kişilerde refraktif ametropinin (miyopi ve hipermetropi) optik olarak düzeltilmesine yöneliktir.

1•DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON® ürünleri ayrıca gözlerin görünüşünü iyileştirmek veya değiştirmek için de tasarlanmıştır.

ACUVUE® Brand Contact Lenses for Astigmatism

Bu ürünler**, Tablo 1**'de gösterildiği gibi Günlük Kullanım veya Uzun Süreli Kullanım için tasarlanmış olup gözünde hastalık olmayan astigmatizması bulunan, fakik veya afakik kişilerde refraktif ametropinin (miyopluk ve hipermetropi) optik olarak düzeltilmesine yöneliktir.

ACUVUE® Brand Contact Lenses for Presbyopia

Bu ürünler, **Tablo 1**'de gösterildiği gibi Günlük Kullanım ve Uzun Süreli Kullanım için tasarlanmış olup gözlerinde hastalık bulunmayan, presbit, fakik veya afakik, 0.75D veya altında astigmatizması bulunan kişilerde, refraktif ametropinin (miyopi ve hipermetropi) optik olarak düzeltilmesine yöneliktir.

ACUVUE OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS ürünleri, ayrıca, aşağıdaki akut ve kronik oküler şartlar için bir bandaj lens olarak terapötik kullanıma da uygundur:

- Entropiyon, trikiyazis, tarsal yaralar ve tekrarlayan kornea yıpranmaları gibi göz kapağı ve kornea yıpranmalarında korneanın korunması için. Ek olarak, sütürler veya oküler yapı şekil bozukluğu, dejenerasyonu veya felci nedeniyle, korneayı tahriş olma veya

tekrarlanan şekilde tahriş olmaya karşı korumanın gerektiği durumlarda koruma sağlamak için de kullanılırlar.

- Büllöz keratopati, epitelyal erozyon ve yıpranma, filamenter keratit ve post-keratoplasti gibi durumlarda kornea ağrısının dindirilmesi için.
- Kronik epitelyal kusurlar, kornea ülseri, nörotropik ve nöroparalitik keratit ve kimyasal yanıklar gibi epitelyal kusurların iyileşme sürecinde bir bariyer olarak kullanmak için.
- Post refraktif cerrahi, lameller greftler, kornea flepleri ve diğer oküler cerrahi şartları gibi bandaj lens kullanımının uygun olduğu ameliyat sonrası koşullar için.
- Kornea ve ilişkili yüzeylerin, kornea sert gaz geçirgen (RGP) lenslerin takılmasına izin vermeyecek şekilde aşırı düzensiz olduğu piggy back lens takma durumlarında yapısal stabilite ve koruma için. Ek olarak, host/grafik birleşimi veya yara dokusunda yükselme farklılıklarının olduğu koşullarda lensin kullanılması tahriş ve yıpranmayı önleyebilir.

ACUVUE OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS ürünleri, terapötik kullanım için reçete edildikleri takdirde, Günlük Kullanım veya Uzun Süreli Kullanım için uygundur.

Tüm ACUVUE® Brand Contact Lenses ürünleri, zararlı UV radyasyonun korneaya ve gözün içine geçmesini önlemeye yardımcı olmak için UV Blokajı (Koruması) içerir.

UYARILAR: UV emici kontakt lensler, gözü ve çevresindeki alanın tamamını kapatmadıkları için UV emici kenarlı gözlükler veya güneş gözlükleri gibi koruyucu UV emici gözlüklerin yerine KULLANILAMAZLAR. UV emici gözlükleri talimatlarında belirtildiği gibi kullanmaya devam etmelisiniz.

Not: UV radyasyonuna uzun süre maruz kalmak katarakt ile ilişkilendirilen risk faktörlerinden biridir. Maruz kalma, çevresel koşullar (rakım, coğrafya bulut örtüsü) ve kişisel faktörler (dış mekanda yapılan etkinliklerin uzunluğu ve yapısı) gibi bir dizi faktöre bağlıdır. Tüm ACUVUE® Brand Contact Lenses ürünleri, zararlı UV radyasyonun korneaya ve gözün içine geçmesine karşı koruma sağlamaya yardımcı olmak için UV blokajlı (korumalı) kontakt lensler içerir. Ancak, UV blokajlı kontakt lens takmanın katarakt ve diğer göz hastalıklarının gelişmesi riskini azalttığını gösteren klinik çalışmalar yapılmamıştır. Daha fazla bilgi için Göz Hastalıkları Uzmanınıza danışın.

KULLANIM PROGRAMI

Hastalar başlangıçta lensi aşırı uzun süre takma eğiliminde olabileceği için, kullanım ve değişim programı, Göz Hastalıkları Uzmanı tarafından belirlenmelidir. Göz Hastalıkları Uzmanı, başlangıçtaki maksimum takma programına uymanın önemini vurgulamalıdır. Ayrıca Göz Hastalıkları Uzmanının belirleyeceği düzenli kontroller de çok önemlidir.

Günlük Kullanım – Gün Boyunca Kullan ve At

Tablo 1'de gösterildiği gibi, Günlük Kullanım – Gün Boyunca Kullan ve At (uyanık haldeyken 24 saatten kısa süreli kullanım) için reçete edilen ACUVUE® Brand Contact Lenses ürünleri, gün boyunca kullanılmak üzere günde bir kez takılacak şekilde tasarlanmıştır ve çıkarıldıktan sonra atılmalıdır. **Bu şekilde kullanıldığında temizleme veya dezenfekte etmek gerekmez.**

1•DAY ACUVUE® TruEye® Brand Contact Lensleri, kontakt lens temizleme veya dezenfeksiyon sistemleri uygulaması ile kullanılmak üzere geliştirilmemiştir. Lensler kullanıldıktan sonra atılmalıdır. Her bir kullanım süresine yeni bir lens ile başlanmalıdır.

Günlük Kullanım - Sık Değiştirme

Günlük Kullanım – Sık Değiştirme (uyanık haldeyken 24 saatten kısa süreli kullanım) için reçete edilen tüm ACUVUE® Vita™ Marka Kontakt Lensler **Tablo 1**'de gösterildiği gibi, her ay atılmalı ve bir yenisiyle değiştirilmelidir.

Günlük Kullanım– Sık Değiştirme için reçete edilen diğer tüm ACUVUE® Marka Kontakt Lensler iki haftada bir atılmalı ve yenisiyle değiştirilmelidir.

Tablo 1'de gösterildiği gibi Günlük Kullanım – Sık Değiştirme başlığı altındaki tüm ACUVUE® Brand Contact Lenses ürünleri, lensin her çıkarılışında temizlenmeli, yıkanmalı ve yalnızca bir kimyasal dezenfeksiyon sistemi kullanılarak dezenfekte edilmelidir.

Uzun Süreli Kullanım

Tablo 1'de gösterildiği gibi Uzun Süreli Kullanım (uyku dahil 24 saatten uzun süreli kullanım) için reçete edilen ACUVUE® Brand Contact Lenses ürünleri, 7 gün/6 gece süreyle sürekli olarak kullanılabilir ve çıkarıldıktan sonra atılmalıdır. Bu şekilde kullanıldığında **temizlik veya dezenfeksiyon gerekli değildir**.

Yeni kontakt lens kullanacak kişinin öncelikle bir Günlük Kullanım – Sık Değiştirme programıyla değerlendirilmesi önerilir. Göz Hastalıkları Uzmanının görüşüne göre, hastanın Uzun Süreli Kullanın için uygun bir aday olduğu saptanırsa, Göz Hastalıkları Uzmanının hastanın yanıtını temel alan bir kullanım programı belirlemesi önerilir.

Çıkartıldıktan sonra lensin bir gece veya daha uzun süreyle dinlenme için göze takılmaması önerilir. Göz Hastalıkları Uzmanı, Uzun Süreli Kullanımın ilk aşamalarında hastayı muayene etmelidir.

KONTRAENDİKASYONLAR

Refraktif ametropi kullanımı için reçete ederken aşağıdaki durumlardan herhangi biri mevcutsa, ACUVUE® Brand Contact Lenses ürünlerini **KULLANMAYIN**.

- Gözün ön kamerasının akut veya subakut enflamasyonu veya enfeksiyonu.
- Kornea, konjunktiva veya göz kapaklarını etkileyen herhangi bir göz hastalığı, yaralanma veya anormallik.
- Lakrimal sekresyonun ciddi oranda yetersiz olması (göz kuruluğu).
- Korneal hipoestezi (kornea hassasiyetinde azalma).
- Kontakt lens takmanın kötüleştirebileceği veya gözü etkileyebileceği herhangi bir sistematik hastalık.
- Kontakt lens takmak veya kontakt lens solüsyonu kullanmak nedeniyle ortaya çıkan veya şiddetlenebilen oküler yüzey veya adnekse ait alerjik reaksiyonlar.
- Sık değiştirme kullanım programı ile reçete edilen lenslerin bakımı için kullanılacak solüsyonun içindeki cıva veya Thimerosal gbi herhangi maddeye olan alerji.
- Herhangi bir aktif kornea enfeksiyonu (bakteri, mantar, protozoal veya virüsün yol açtığı).
- Göz kızarıklığı veya gözün tahriş olması.

Göz Hastalıkları Uzmanı, TERAPÖTİK KULLANIM AÇISINDAN, yukarıda adı geçenleri de içerebilecek belirli oküler şartların iyileşme sürecine yardımcı olması amacıyla, ACUVUE OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS ürünlerini reçete edebilir.

UYARILAR

(Günlük Kullanım = 24 saatten az, uyanıkken; Uzun Süreli Kullanım = 24 saatten fazla, uyuma süresi dahil).
Kontakt lenslerin ve lens kutuları dahil lens bakım ürünlerinin doğru kullanım ve bakımı, güvenli kullanım açısından temel esastır. Kontakt lenslerin veya lens bakım ürünlerinin kullanımından kaynaklanan sorunlar, gözde ciddi yaralanmalara neden olabilir.

Hastalara kontakt lens kullanımıyla ilgili aşağıdaki uyarılar iletilmelidir:

- ACUVUE Marka Günlük kullan at lensler tek sefer günlük kullanım için reçete edilirler. Çalışmalar lens bakımı ve kullanımı ile ilişkili diskonfor ve enflamasyonda içeren bazı komplikasyonların günlük kullan at yumuşak kontakt lensler ile azaldığını göstermiştir ve tekrar kullanım bu problemlerin oluşmasından daha büyük riske yol açmaktadır.
- Kontakt lens veya lens bakım ürünleriyle ilgili sorunlar, gözde ciddi yaralanmalara neden olabilir. Hastalar, kontakt lenslerin ve lens kutuları dahil lens bakım ürünlerinin

doğru kullanım ve bakımının, bu ürünlerin güvenli kullanımı açısından temel esas olduğu hususunda uyarılmalıdır. †

- Kornea ülserleri dahil olmak üzere göz sorunları hızlı bir şekilde gelişebilir ve görme kaybına neden olabilir.
- Çalışmalar, ülseratif keratit riskinin, uzun süreli kullanılan lens kullanıcıları için günlük kullanılan lens kullanıcılarına göre daha yüksek olduğunu göstermiştir.
- Günlük lens kullanıcıları lenslerini geceleri de çıkartmadan kullanıyorlarsa (onaylı endikasyonun dışında), bu kullanıcılar için ülseratif keratit riski lensi geceleri kullanmayanlara göre daha yüksektir.
- Genel ülseratif keratit riski, lens kutusunun temizlenmesi de dahil olmak üzere lens bakım talimatlarına dikkatle uyulması yoluyla azaltılabilir.
- Çalışmalar, sigara içen kontakt lens kullanıcıları için ülseratif keratit riskinin sigara içmeyen kullanıcılara göre daha yüksek olduğunu göstermiştir.
- Kontakt lenslerinizi ,yüzerken , diğer su sporları yaparken veya banyo esanasında suya maruz bırakmayın bu micro organizmaların neden olduğu ciddi göz enfeksiyon riskini artırır ve görme kaybına neden olabilir. Eğer lensleriniz ile suya dalarsanız , hasta lenslerini çıkarmalı ve yeni bir çift lens ile değiştirmelidir . Su içinde yapılan herhangi bir aktivite de lenslerin kullanılabilmesi ile ilgili tavsiye almak için bir göz sağlığı uzmanına danışılmalıdır

Hasta, göz rahatsızlığı, aşırı göz yaşarması, görmede değişiklikler, gözde kızarıklık veya diğer sorunlar yaşarsa, kontakt lensleri hemen çıkartmaları söylenmeli ve lensi kullanan kişi acilen Göz Hastalıkları Uzmanıyla iletişim kurmalıdır. Kontakt lens kullanıcılarının, talimatlarda belirtildiği gibi rutin olarak Göz Hastalıkları Uzmanına kontrole gitmeleri önerilir.

***† New England Journal of Medicine, 21 september, 1989,* 321 (12), s. 773-783**

ÖNLEMLER

Sorun görüldüğünden yapılması gerekenler

LÜTFEN HASTANIZA KONTAKT LENSLERİ HEMEN ÇIKARTMASINI VE GÖZ HASTALIKLARI UZMANINDAN TIBBİ YARDIM ALMASINI SÖYLEYİN.

Göz Hastalıkları Uzmanları için Özel Önlemler

Lenslerin klinik araştırmalarında çok fazla sayıda insan yer almadığı için, tüm refraktif güçler, tasarım yapılandırmaları veya lens malzemelerindeki lens parametreleri, değerlendirme açısından anlamlı sayılar üzerinde değerlendirilmemektedir. Bu nedenle, Göz Hastalıkları Uzmanının uygun lens tasarımı ve parametrelerini seçerken lensin oksijen iletebilirliği,

ıslanabilirlik, merkezi ve periferik kalınlık ve optik alan çapı gibi lens performansını ve oküler sağlığı etkileyebilecek bütün niteliklerini göz önüne almalıdır.

Bu faktörlerin hastanın oküler sağlığı üzerindeki potansiyel etkisi, hastanın refraktif düzeltme ihtiyacı karşısında dikkatlice tartılmalıdır. Bu yüzden hastanın devam eden oküler sağlığı ve göz üzerindeki lensin performansı Göz Hastalıkları Uzmanı tarafından dikkatlice izlenmelidir.

- Kozmetik olarak renklendirilmiş lenslerde ışık geçişinin azalmış olmasına bağlı olarak *1•DAY* ACUVUE® DEFINE® Brand Contact Lenses with LACREON® kullanan hastaların bazıları kullanım sırasında görme ile ilgili semptomları tecrübe edebilirler. Ek olarak bazı hastalar opak iris paternine bağlı çevresel görüşte daha duyarlı olabilirler.
- Monovizyon veya multifocal kullanarak presbiyopiyi düzeltmek için ACUVUE® Brand Contact Lenses ürünlerini kullanan hastalar, uzağı veya yakını görmek için en iyi düzeltilmiş görüş keskinliğine erişemeyebilir. Görmeyle ilgili gereksinimler kişiden kişiye değişir ve her bir hasta için en uygun lens türünü seçerken göz önüne alınmalıdır.
- Sarı renkli bir boya olanflorosein, lensler takılıyken kullanılmamalıdır. Lensler bu boyayı emer ve renkleri bozulur. Gözlerde florosein kullanıldığı durumlarda, gözde kullanım için önerilen steril bir tuz solüsyonuyla gözler yıkanmalıdır.
- Göz Hastalıkları Uzmanı, hastaya gözlerin kızarması veya tahriş olması durumunda lensleri derhal çıkarması yönünde talimat vermelidir.
- Göz Hastalıkları Uzmanı, aşağıdaki bakım rejimi ve güvenlik önlemleri hakkında hastayı itinayla bilgilendirmelidir.

Lenslere Dokunmayla İlgili Önlemler

- Göz Hastalıkları Uzmanının yanından ayrılmadan önce hastanın lensleri uygun bir şekilde takıp çıkartabildiğinden veya bunu hastanın yerine yapabilecek bir başkasının hastaya yardımcı olabileceğinden emin olunmalıdır
- Steril blister ambalaj açılmışsa veya hasar görmüşse **KULLANMAYIN**.
- Kontakt lenslere dokunmadan önce eller yıkanmalı ve durulanmalıdır. Kozmetik malzeme, losyon, sabun, krem, deodorant veya spreyleri gözler veya lenslerle temas etmemelidir. Lensleri makyaj yapmadan önce takmak en iyisidir.
- Lensler üzerinde görüşün bozulması ve/veya göze zarar gelmesine neden olacak şekilde mikroskobik çizilmeler oluşabileceğinden, ellerde yabancı maddeler varsa kontakt lenslere el veya parmaklarla dokunulmaması gerekir.
- ACUVUE® Brand Contact Lenses ürünlerinin ve Göz Hastalıkları Uzmanının reçete ettiği ürünlere ait “Hasta Talimat Kılavuzu” içindeki kullanım, yerleştirme, çıkarma, temizleme, dezenfekte etme, saklama ve kullanım talimatlarına itinayla uyulmalıdır.
- Lensler her zaman itinayla tutulmalı ve düşürülmemelidir.

- Lensi kabından çıkartmak için asla cımbız veya başka bir alet kullanmayınız. Lensi, kabın yan yüzeylerinden kaydırarak dikkatlice çıkartın.
- Lenslere tırnaklarla dokunulmamalıdır.
- Tüm ACUVUE® OASYS® Brand Contact Lenses with HYDRACLEAR® PLUS ürünlerinin Terapötik kullanımı yakından denetim gerektirir. Bandaj lensi ile tedavi sırasında kullanılan oküler ilaçlar Göz Hastalıkları Uzmanı tarafından yakından izlenmelidir. Bazı oküler durumlarda, lensleri yalnızca Göz Hastalıkları Uzmanı takmalı ve çıkarmalıdır. Bu tür durumlarda, hastalara lenslere dokunmamaları için talimat verilmelidir.

Lens Kullanımıyla İlgili Önlemler

- Lens göze yapışıyorsa (hareket etmiyorsa), "Yapışan (hareket etmeyen) lensler için bakım" bölümündeki tavsiye edilen talimatlara bakın. Gözün sağlığını korumak için lensin göz üzerinde serbestçe hareket etmesi gerekir. Lens halen hareket etmiyorsa, hastaya hemen Göz Hastalıkları Uzmanına danışması yönünde talimat verilmelidir.
- Lensler asla Göz Hastalıkları Uzmanı tarafından tavsiye edilen süreden daha uzun bir süre takılmamalıdır.
- Lensler takılıyken saç spreyi gibi aerosol ürünler kullanılırsa, dikkatli olunmalı ve sprey çökene kadar gözler kapalı tutulmalıdır.
- Lens takarken her tür zararlı veya tahriş edici buhar veya dumandan uzak durulması gerekir.
- Asla başkalarının lenslerinizi takmalarına izin vermeyin. Lensleri paylaşmak, göz enfeksiyonlarının görülme olasılığını büyük ölçüde artıracaktır.
- Önerilen kullanım programının ardından, her zaman, takılan lensleri Göz Hastalıkları Uzmanı tarafından reçete edildiği şekilde atın.

Solüsyonla İlgili Önlemler

- Farklı solüsyonlar her zaman bir arada kullanılamaz ve her solüsyonun bütün lenslerle birlikte kullanılması güvenli değildir. Yalnızca önerilen solüsyonları kullanın.
- Hasta göz doktoruna danışmadan solusyonlarını değiştirmemelidir.
- Sert gaz geçirgen (RGP) kontakt lensler için önerilen solüsyonları asla kullanmayın.
- Her zaman, yeni, kullanım süresi geçmemiş lens bakım solüsyonları kullanın.
- Her zaman kontakt lens solüsyonlarının kullanımına yönelik prospektüslerdeki talimatları izleyin.
- Yalnızca (ısı değil) kimyasal lens bakım sistemi kullanın. Isı (termal) bakım sistemi ACUVUE® Brand Contact Lenses ürünlerine zarar verebilir.
- Kullanıldıkları takdirde, steril korunmayan solüsyonlar talimatlarda belirtilen süre sonunda atılmalıdır.

- Lensleri kayganlaştırmak veya ıslatmak için önerilen solüsyonlar dışında hiçbir şey veya tükürük kullanmayın.
- Lensleri kullanılmadığı zamanlarda (saklarken) önerilen saklama solüsyonu içine tam olarak batmış bir şekilde bekletin. Uzun süreli kuruma lens yüzeylerinin ıslatılabilir duruma gelme becerisini azaltır. Lens yüzeyi kuruduğu takdirde "Kurumuş (susuz kalmış) lensler için bakım" bölümündeki talimatları izleyin.

Lens Kutusuyla İlgili Önlemler

Lens kutuları bakterilerin üreyebileceği bir kaynak olabilir ve lens kutusu üreticisinin veya Göz Hastalıkları Uzmanının önerdiği gibi düzgün bir şekilde kullanılmalı, temizlenmeli ve düzenli aralıklarla değiştirilmelidir.

Hastalarla Konuşulması Gereken Diğer Konular

- Bazı hastalar kozmetik olarak boyanmış lenslerin ışık iletiminde azalma hissedebildiği için, kimi hastalar *1•DAY* ACUVUE® DEFINE® Brand Contact Lenses with LACREON® taktıklarında bazı belirtiler hissedebilir. Ayrıca, opak iris modeli sebebiyle kimi hastalar periferal rahatsızlık da hissedebilir.
- Göz için herhangi bir ilaç veya göz damlası kullanılmadan önce her zaman Göz Hastalıkları Uzmanına danışılmalıdır. Antihistaminikler, dekonjestanlar, diüretikler, kas gevşeticiler, sakinleştiriciler ve hareket bozuklukları na yönelik ilaçlar gibi belirli ilaçlar, göz kuruluğuna, lense karşı duyarlılıkta artışa veya bulanık görmeye neden olabilir. Bu tür durumlar söz konusuysa, uygun tedavi önlemlerine başvurulmalıdır
- Oral kontraseptif kullananlarda, kontakt lens kullanırken görmede ve lense karşı duyarlılıkta değişiklikler görülebilir. Hasta gerektiği gibi ikaz edilmelidir.
- Bütün lensler için olduğu gibi, hastanın göz sağlığının sürekli olarak korunmasını sağlamak için takip amaçlı görüşmeler gereklidir. Hastaya takip amaçlı görüşme programı önerisi hakkında bilgi verilmelidir.

Hastanın Kontakt Lens Taktığını Kimlerin Bilmesi Gerekir?

- Doktorlara (Göz Hastalıkları Uzmanları ve diğer uzmanlık alanındaki doktorlar) hastanın kontakt lens kullanıcısı olduğu konusunda bilgi verilmelidir.
- Hastanın işverenine kontakt lens kullandığı hususunda bilgi verilmelidir. Bazı işler, göz koruma cihazlarının kullanılmasını veya hastanın kontakt lens kullanmamasını gerektirebilir.

YAN ETKİLER

Hasta, ACUVUE® Brand Contact Lenses ürünleri kullanırken aşağıdaki sorunların görülebileceği hususunda bilgilendirilmelidir:

- Gözler yanabilir, batma ve/veya kaşınma olabilir.
- Lens göze ilk kez yerleştirildiğinden daha az bir rahatlık hissi olabilir.
- Gözde bir şey varmış gibi hissedilebilir (yabancı cisim, göz bölgesinin kaşınması).
- Periferik infiltrat, periferik kornea ülserleri ve kornea yıpranması nedeniyle bazı geçici bozukluklar görülebilir. Lokal veya genel ödem, kornea neovaskülarizasyonu, kornea lekelenmesi, enjeksiyon, tarsal anormallikler, iritis ve konjunktivit gibi (bunların bazıları, düşük düzeylerde klinik olarak kabul edilebilirdir) diğer fizyolojik anormallikler de görülebilir.
- Aşırı sulanma, olağan olmayan gözyaşı sekresyonu veya göz kızarıklığı oluşabilir.
- Lenslerin sürekli olarak veya çok uzun bir süre takılması durumunda görüş keskinliği bozulması; bulanık görüş; nesnelerin etrafında ışık halkası veya gökkuşağı benzeri görüntüler görme veya göz kuruluğu semptomları oluşabilir.

Hastalardan her gün en az bir kez 3 adımdan oluşan bir kontrol yapmaları istenmelidir. Kendilerine şunları sormaları gerekir:

- Gözümdeki lensler nasıl hissediyorum?
- Gözlerim nasıl görünüyor?
- Görüşümde bir değişiklik hissettim?

Hasta bir sorun olduğunu bildirirse, **LENSLERİ DERHAL ÇIKARMASI** talimatı verilmelidir. Rahatsızlık veya sorun geçerse, hasta lense dikkatlice bakmalıdır. Lens herhangi bir şekilde hasar görmüşse, hasta lensi tekrar gözüne **TAKMAMALIDIR**. Hasta lensi atmalı ve gözüne yeni bir lens takmak için başvurmalıdır.

Lens kirlenmişse, üzerinde kirpik veya yabancı bir şey varsa ya da problem geçmiş ve lens hasar görmemişse lensi atmalı ve yeni bir lens takmalıdır. Sorun devam ederse hasta lensi tekrar **TAKMAMALI** bunun yerine **HEMEN GÖZ HASTALIKLARI UZMANINA BAŞVURMALIDIR**.

Hastaya, sorunu kendisi çözmek için yeni bir lens **KULLANMAMASI** talimatı da verilmelidir. Hasta, yukarıdaki belirtilerin oluşması durumunda, enfeksiyon, kornea ülseri, neovaskülarizasyon veya iritis gibi ciddi bir durum olabileceği konusunda uyarılmalıdır. Hastaya, sorunun uzmanlarca belirlenmesi ve göze gelebilecek ciddi bir zarardan korunması için hemen tıbbı yardım alması gerektiği söylenmelidir.

Terapötik kullanım sırasında karşılaşılan yan etki, orijinal hastalığa veya yaralanma ya da kontakt lens kullanmanın etkisi sonucu ortaya çıkabilir. Önceden hastalıklı bir gözü tedavi etmek amacıyla terapötik kullanım için yumuşak kontakt lens kullanıldığında mevcut bir hastalığın ya da sağlıkla ilgili bir durumun kötüleşmesi olasılığı vardır. Hastaya, lens kullanılırken semptomlarda bir kötüleşme olması durumunda gözün ciddi bir şekilde zarar görmemesi için **HEMEN** bir Göz Hastalıkları Uzmanına başvurması talimatı verilmelidir.

Lens bakım talimatları

Lens verilirken Göz Hastalıkları Uzmanı, hastanın lensinin türü ve kullanma programına göre hastaya yeterli ve uygun uyarılar yapmalı ve talimat vermelidir. Göz Hastalıkları Uzmanı, hastanın kişisel gereksinimlerine göre uyarlanmış, uygun bir bakım sistemi önermelidir.

Lens bakımında doğru yöntemin izlenmemesi gözlere ciddi bir şekilde zarar verebilir. **"Uyarılar"** bölümünde bunların ayrıntıları açıklanmıştır.

Kontakt lenslerin kullanımı, bakımı, temizlenmesi, dezenfekte edilmesi ve saklanması konusunda kapsamlı bilgi almak için ACUVUE® Brand Contact Lenses ürünlerine yönelik Hasta Talimat Kılavuzuna bakın.

ACUVUE® Brand Contact Lenses ürünleri, **Tablo 1**'de gösterildiği gibi, sık değiştirme için önerilmişse, lensler çıkarıldıktan sonra ve yeniden kullanılmadan önce temizlenmeli ve dezenfekte edilmelidir. Lensler, yalnızca bir kimyasal dezenfeksiyon sistemi kullanılarak (örn. çok amaçlı sistem veya hidrojen peroksit sistemi) dezenfekte edilebilir.

Göz Hastalıkları Uzmanı, lens kutusu temizliği ile ilgili temel bilgiler ve hasta için önerilen lens bakım programı ile ilgili özel talimatlar dahil olmak lens bakım talimatlarını hastayla birlikte incelemelidir. Bazı lens malzemeleri, **Tablo 1**'de gösterildiği gibi, silikon içerdiği için farklı lens bakım ürünleri kullanıldığında ıslanabilirlikte değişiklikler gözlenebilir.

Yapışan (hareket etmeyen) lens için bakım

Lens yapışıyorsa (hareket etmiyorsa) hasta, önerilen gözyaşı damlası veya sulandırma solüsyonundan doğrudan gözüne birkaç damla damlatması ve çıkartmadan önce lensin serbest bir şekilde hareket etmesini beklemesi yönünde uyarılmalıdır. Birkaç dakika sonra lens halen hareket etmiyorsa, hasta hemen Göz Hastalıkları Uzmanına danışmalıdır.

Kurumuş (susuz kalmış) lens için bakım

ACUVUE® Brand Lens ürünleri uzun bir süre için gözden çıkartılmışsa yüzeyi kuruyabilir ve giderek ıslatılamaz bir hale gelir. Bu durum meydana gelirse, lensi atın ve yenisini kullanın.

ACİL DURUMLAR

Herhangi bir kimyasal türünün (evde kullanılan ürünler, bahçe işlerinde kullanılan solüsyonlar, laboratuvar kimyasalları vb.) gözlere sıçraması durumunda, hasta, aşağıdaki işlemleri yapması gerektiği hususunda bilgilendirilmelidir: **GÖZLERİNİZİ HEMEN SUYLA YIKAYIN VE GÖZ HASTALIKLARI UZMANINDAN TIBBİ YARDIM ALIN VEYA GECİKMEKSİZİN BİR HASTANENİN ACİL SERVİSİNE GİDİN.**

TERS ETKİLERİN BİLDİRİLMESİ

ACUVUE® Brand Contact Lenses ürününü kullanan hastalarda gözlemlenen veya lenslerle ilgili olarak görülen ciddi düzeydeki tüm ters etki ve sorunlar aşağıdaki adrese bildirilmelidir:

Johnson & Johnson Sihhi Malzeme San. ve Tic. Ltd. Şti.
Mehmet Özçelik İşmerkez Ertürk Sok. No:5
34810 Kavacık - Beykoz / İstanbul
Tel: 0216 680 37 81
Faks: 0 216 331 08 06

Ek bilgiler

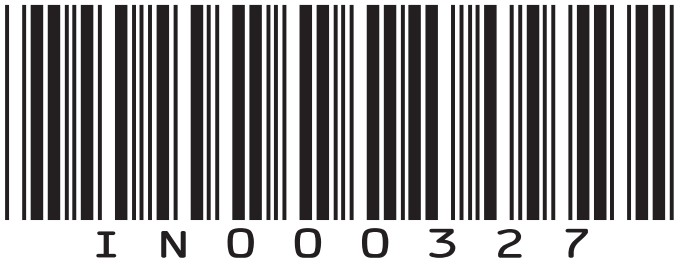
ACUVUE® Brand Contact Lens ürünleriyle ilgili ek bilgiler almak ve ACUVUE® Brand Contact Lenses ürünlerine yönelik Hasta Talimat Kılavuzlarının ücretsiz kopyasını edinmek için yukarıdaki adresteki Müşteri Hizmetleri ile iletişim kurabilirsiniz.

Üretici:
Üretim tesisi için lütfen kutuya bakın

USA:
Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville
Florida, 32256
USA

IRELAND:
Johnson & Johnson Vision Care (Ireland)
The National Technology Park
Limerick
Ireland

AB Yetkili Temsilcisi:
Johnson & Johnson Medical Limited
Pinewood Campus
Nine Mile Ride
Wokingham
RG40 3EW
United Kingdom
www.acuvue.com



ACUVUE®
Brand Contact Lenses Package Insert
(English, German, Dutch & Turkish)
IN000327

Revision date: August 2017

APPENDIX D: [redacted]

[redacted] Lens Fitting Characteristics
Patient Reported Outcomes

[redacted] LENS FITTING CHARACTERISTICS

[redacted]

Lens Fitting Characteristics

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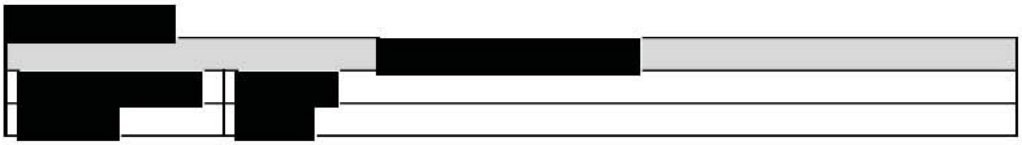

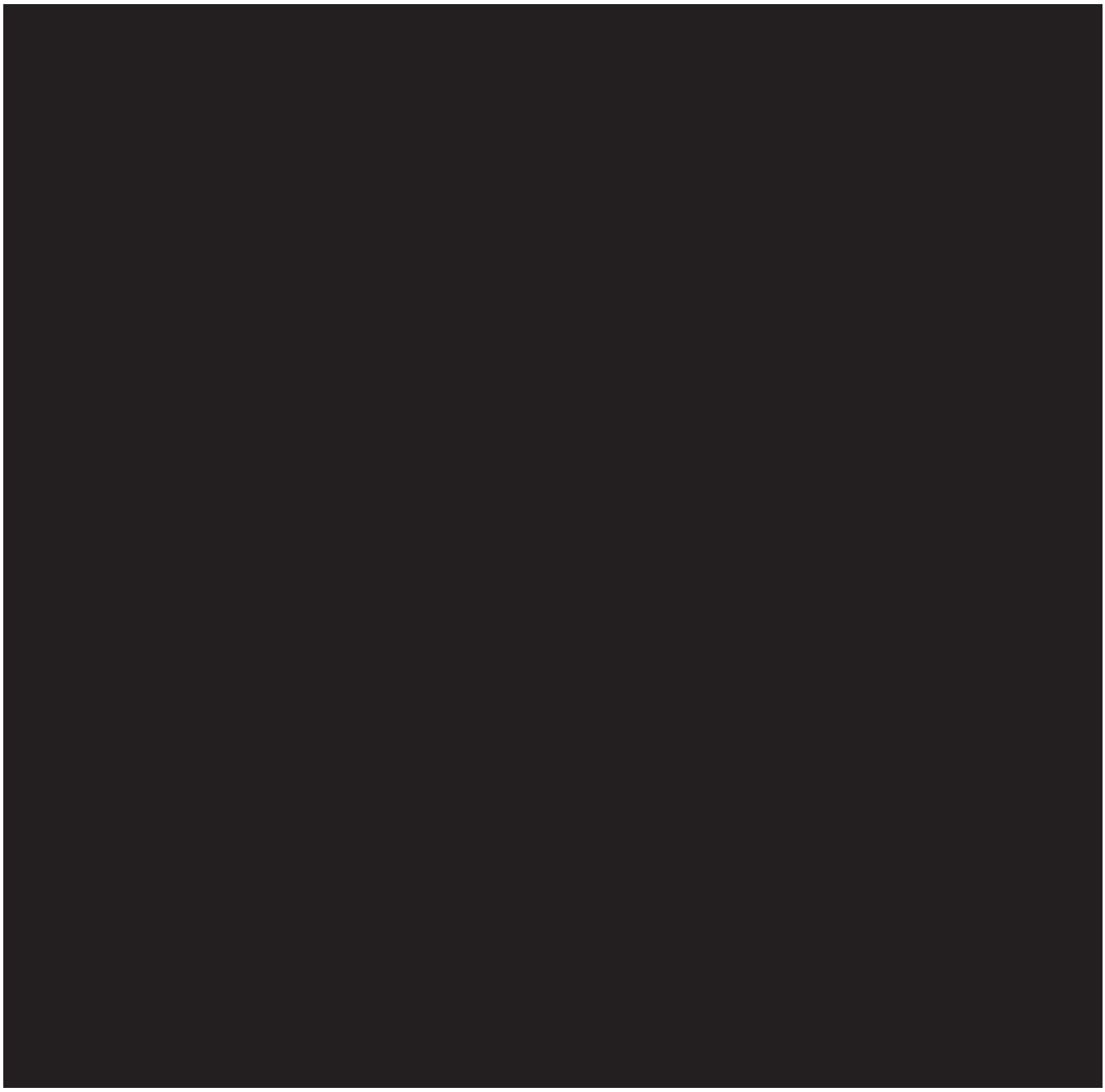

[redacted] PATIENT REPORTED OUTCOMES

[redacted] **Patient Reported Outcomes**

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

APPENDIX E: METHODOLOGY FOR PREPARATION AND OCULAR INSTILLATION OF FLUORESCENT MICROSPHERES

Methodology for the ocular instillation of fluorescent microspheres

1) 1ml of 1% microsphere solids suspension (G0100B Fluoro-Max Dyed Green Aqueous Fluorescent Particles, Thermo Scientific, USA) will be dispensed into a 1.5ml microcentrifuge tube.
2) The microcentrifuge tube and contents will then undergo disinfection by pasteurization at 78 – 80ºC for 24 hours as recommended by the manufacturer (https://www.thermofisher.com/uk/en/home/life-science/cell-analysis/qdots-microspheres-nanospheres/idc-surfactant-free-latex-beads/latex-bead-technical-overview/working-with-latex-beads.html).
3) The microcentrifuge tube will be centrifuged at 6200 rev/min (Mini-Centrifuge Gilson GmCLab) until a pellet of microspheres is formed. The liquid will be removed using a Gilson automated micropipette (with a sterile pipette tip) and sterile ophthalmic phosphate buffered saline solution (CooperVision Inc.) will be added to form a 1% solids suspension.
4) The microcentrifuge tube will be stored for up to one week in a laboratory refrigerator (5 ± 4°C). After one week the microcentrifuge tube and contents will be discarded and a new microsphere suspension will be prepared.
5) Following removal from the refrigerator, the microcentrifuge tube will be agitated at 3000 rev/min for 5 minutes (Grant-bio PV-1 Vortex Mixer, UK) to ensure an even distribution of the microspheres in the suspension.
6) A Gilson automated micropipette will then be used to draw up 3µl of microsphere suspension into a sterile pipette tip.

For dispensing of microsphere suspension directly onto ocular surface:

1) The subject will be instructed to look inferior nasally and 3µl of microsphere suspension will be dispensed into the tear film overlying the superior temporal conjunctiva, approximately 1 mm from the limbus.

For dispensing of microsphere suspension onto the back surface of a contact lens prior to application (RE Only):

1) The contact lens will be carefully removed from the blister pack using tweezers and held vertically for 3 seconds to allow the surface packaging solution to pool on the

lower lens edge. This lower lens edge will be then briefly dipped into the blister packaging solution to break the surface tension and allow the majority of the surface packaging solution to flow back into the blister.

2) The contact lens will then be placed on the subject's index finger and 3µl of microsphere suspension dispensed onto the posterior lens surface.
3) If required, the subject can choose to wear a medical glove / cot to minimize adhesion of the lens to the subject's finger.
4) The subject will be asked to apply the lens whilst facing directly downwards, maintaining the contact lens in a horizontal position to avoid spilling any of the microsphere suspension.
5) The subject will then be instructed to apply the lens directly onto the cornea and not to move the lens off the cornea during wear.

For contact lens dispensing only (LE Only):

1) The study contact lens will be applied by the subject and worn for 10 minutes.
2) The subject will be instructed to look inferior nasally and 3µl of microsphere suspension will be dispensed into the tear film overlying the superior temporal conjunctiva, 1 mm from the lens edge.

APPENDIX F: EUROLENS RESEARCH SOP 'THE SET-UP, MEASUREMENT OF VISUAL ACUITY AND PROCEDURES FOR CARRYING OUT AN OVER REFRACTION USING THE EUROLENS COMPUTERIZED LOGMAR VA CHART'

Eurolens Research

Clinical
Standard Operating Procedure

The set up, measurement of visual acuity and procedures for carrying out an over refraction using the Eurolens computerised logMAR VA chart

Neil Chatterjee
Research Optometrist

First issued: v0; July 8, 2009
Reviewed (with changes): v1; February 7, 2014
Reviewed (no changes): v1; February 2, 2016
Reviewed (with changes): v2; December 19, 2017

Document control

Title:	The set up and measurement of visual acuity using the Eurolens computerised logMAR VA chart
Document type:	Clinical standard operating procedure
Number of pages:	11

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Neil Chatterjee,
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Document reviewed by: _____ Date: 19 Dec 2017

Gillian Howarth,
Research Optometrist

Document reviewed and approved by: _____ Date: 22 Dec 2017

Michelle Inwood,
Project Officer

Document approved by: _____ Date: 12-Jan-2018

Philip Morgan,
Director

Summary

This document contains details of:

1. Overview of chart design.
2. The procedure of calibration and set up of the Eurolens computerised logMAR chart.
3. A method of measurement of VA using the Eurolens chart.
4. A method of carrying out an over refraction for clinical study contact lenses when visual performance is being measured using the Eurolens chart at 6m.

Responsibilities

GOC-registered study investigators/research optometrists.

Definitions/Acronym

logMAR - logarithmic value of the minimum angle of resolution.

The MAR relates to the resolution required to resolve the elements of a letter. logMAR is the $\log_{10}$ of the MAR. (**Table 1**)

Snellen	Decimal	MAR	logMAR
6/60	0.10	10	1.00
6/24	0.25	4	0.602
6/12	0.50	2	0.301
6/6	1.00	1	0.000
6/4	1.50	0.667	-0.176

Table 1. The relationship between different acuity measurements

Optotype – A standardised symbol for testing vision.

Over refraction – the amount, in Dioptres (D), that will be accepted by a subject over a contact lens in order to obtain the optimum visual performance when viewing a visual acuity test chart.

Chart design

1. The Eurolens computerised logMAR visual acuity chart (hereafter referred to as Eurolens chart) is a logMAR chart designed to run on an Apple Macintosh with

Microsoft Excel software. The chart is displayed through an external monitor connected to the Apple Mac via its monitor socket and appropriate cable.

2. The Eurolens chart is similar in design to the traditional Bailey-Lovie logMAR chart, however it uses a reversed Sloan font as the optotype. The need for the reversed font is due to the chart being viewed indirectly in a mirror in a 3m consulting room. The chart is mounted on an adjustable mount, above the subject's head.
3. The indirect viewing makes the effective distance of the chart 6m from the subject. This 6m distance is the standard testing distance in optometric practice.
4. High (100%) and low (10%) contrast VA measurements can be taken with the chart.
5. The VA measurement from the Eurolens chart is intended to be equivalent to that obtained from the traditional Bailey-Lovie logMAR charts at 6m. The Eurolens chart has two advantages over the Bailey-Lovie. The Eurolens chart does not fade or discolour (which reduces legibility). Further, unlike the fixed Bailey-Lovie chart, the letters can be randomised on the Eurolens chart, which reduces the effect of memory influencing the subject's VA score.

Initial computer set up

1. The Apple Macintosh should have the following installed:
    a. Reversed Sloan font (otf file, which should be copied to the Macintosh HD/Library/Fonts/ folder)
    b. Microsoft Office 2011 or later
    c. Eurolens chart v5 software
2. The external monitor should be connected to the Mac. It will require the use of an appropriate adaptor and cable.
3. The additional monitor should be recognised automatically by the Mac. The Mac should configure the monitor as a second desktop. To verify this, move the mouse pointer across the screen. It should be possible to move the mouse pointer off the edge of the main screen and it should appear on the external monitor.
4. The Eurolens Chart software is an Excel file called Eurolens Research chart.xls. This, for convenience, is located on the desktop.
5. To run the chart, open the Excel file. Click on "enable macros".
6. The chart should be displayed on the external monitor and the chart's control panel should appear on the Mac's main screen (**Figure 1**).

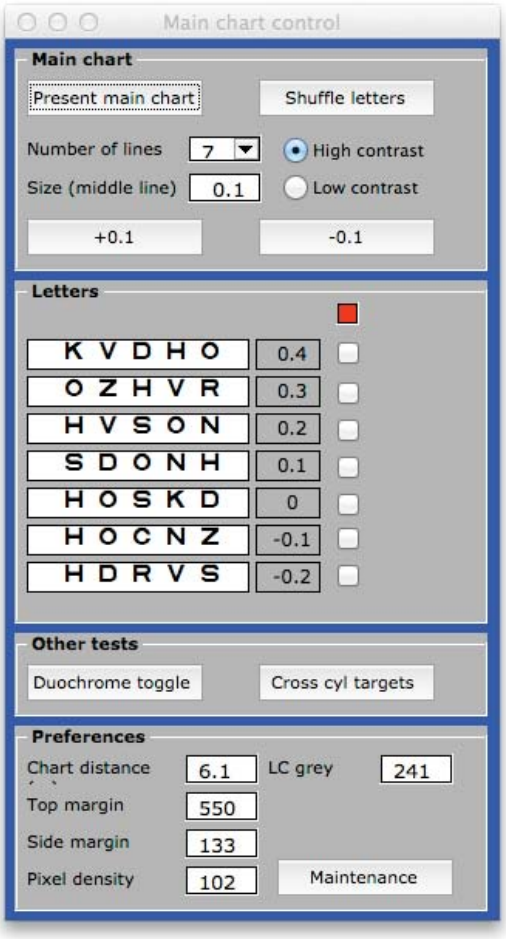

Figure 1. Chart control panel

7. If the letter chart appears on the Mac's main screen, it will need to be "dragged" onto the external monitor. To do this the chart control box must be closed. The main chart can now be dragged onto the second screen and maximised.
8. To restart the control panel, click on the Excel icon in the dock. Then in Excel's menu, select.: Tools -> Macro-> Macros. A macro box should appear, select the macro entitled 'showform' and click on run. The chart's control panel can be reopened if closed (e.g. accidentally) by repeating this step.

Chart calibration procedure

1. It is important the charts are calibrated before first use, to ensure the optotypes are of the correct size and contrast. Minute adjustments of monitor contrast or brightness can affect the contrast of the letters (especially low).

2. If the chart distance is set to 6m, the 0.8 letter on the computer chart should be the same height as that on the Bailey-Lovie chart, measuring just under 55mm high.
3. The chart distance should then be set to the distance of the subject's head to the chart.
4. The monitor should be inclined downwards at an angle of approximately five degrees from the vertical. The reason being the contrast of an LCD monitor can vary with tilt. At five degrees of inclination, the monitor will be 'straight on' for the subject sat on the chair below. (see Appendix A)
5. The monitor should then be calibrated using a Datacolor Spyder 4. Whilst calibrating, the room lights should be on full illumination and the monitor set to factory default values (all setting "standard"). The corresponding monitor profile file generated should be saved and then used as the profile for the external monitor.
6. The contrast of the low contrast chart should be measured. The test spreadsheet (low contrast grey test.xlsx) should be displayed on the monitor with room lights on. Measurements of the luminance of the grey and white halves are taken with the spyder. The luminance measurements are then averaged. The contrast of the grey to white backgrounds is calculated as follows:

$$\% \text{ contrast} = \frac{\text{white lum} - \text{grey lum}}{\text{white lum}} \times 100$$

7. The RGB vales of the grey background should be altered until the contrast is calculated to be approximately 10%. This value is usually between 240 and 245 units.
8. Acuity measurements on the freshly calibrated chart should then be compared to those taken with two already calibrated charts. This is done by measuring high and low contrast visual acuity with all three charts (in a randomised order on around eight subjects). The acuity measurements of the three charts should all agree within two letters (0.04 logMAR) for high and low contrast acuity.
9. If the high contrast acuity on the test chart does not agree with that of the control charts, then the "chart distance" value should be altered on the test chart, until it is in agreement with the controls.
10. Once the high contrast acuity values are in agreement, the test chart's low contrast acuity should be in agreement with the control. If not then the "LC grey" value should be altered on the test chart until agreement is reached.

11. Final settings for each monitor on 11 October 2017 are contained in Appendix B.

Measurement of VA using the Eurolens chart

General instructions

1. The subject should be seated in the chair 3m from the mirror. This will place the chart at a 6m testing distance.
2. The default test chart for standard testing should be a 7-line chart ranging from 0.4 to -0.2 (Figure 1).
3. The subject's acuity can be tested monocularly and/or binocularly according to the study protocol.
4. If the subject cannot read the top line then increase letter size in 0.1 steps until the subject can see the top line.
5. Adjusting the "number of lines" box can alter the number of rows of letters displayed on the chart. Please note to display larger letters (over 0.4), then only one or three rows should be selected.
6. Letters can be increased in size by 0.1 steps, by clicking on the "+0.1" box. Letters can be increased in size to a maximum of 1.0.
7. Letters can be decreased in size by clicking on "-0.1".
8. The control panel displays information on the optotypes currently displayed on the chart and their size in logMAR.
9. The VA score is calculated using the same method as a traditional Bailey-Lovie chart, with each letter scoring 0.02 units and each complete line scoring 0.1 (see below).
10. To display the high contrast chart select "high contrast", similarly to display the low contrast chart select "low contrast". This will display letters of 100% and 10% contrast respectively
11. The Mac generates the sequence of letters used in the chart randomly. Clicking on "shuffle letters" can change the sequence of letters.
12. Letters should be shuffled after each VA measurement to avoid the subject learning the chart.
13. As the chart is at 6m, any over-refraction performed can be considered to be equivalent to that performed on a 6m Snellen chart i.e. at infinity.

14. The 6m testing distance should also be taken into account when comparing logMAR scores obtained with the Bailey-Lovie chart at 3m. The Bailey-Lovie scores should differ by -0.3.

Subject instructions (standard chart display)

After positioning the subject at the desired test distance, initiate the testing as follows:

1. Ask the subject to read the smallest line where they feel they can easily read all the letters. If the subject reads all the letters on the initial line, encourage them to continue reading the smaller lines until three or more letters on a 5- letter line are incorrectly identified.
2. If the subject identifies one letter incorrectly on the initial line, ask them to read the line(s) above until one complete line has been identified correctly. Then encourage the subject to continue reading the smaller lines/letters until three or more letters on a 5-letter line are incorrectly identified*. Note: The subject is to be encouraged to read and even guess at the letters until three or more letters are incorrectly identified.*

Scoring

To determine the VA unit score for a given line: Take the maximum VA for the last line read (i.e. the line on which three or more letters were missed) and add +0.02 for every letter missed on the chart.

For example:

i)	0.00 line	3 letters missed	logMAR score +0.06
ii)	+0.20 line	0 letters missed	
	+0.10 line	2 letters missed	
	0.00 line	3 letters missed	logMAR score +0.10
iii)	-0.20 line	0 letters missed	
	-0.30 line	2 letter missed	
	-0.40 line	4 letters missed	logMAR score –0.28

Over-refraction

Unless the clinical study protocol states otherwise the following procedures should be carried out:

1. Visual acuity using the Eurolens chart will be measured with no over-refraction in place. The study protocol may require that this be carried out monocularly or binocularly.
2. A binocular over-refraction should be carried out using the chart at 6m. This procedure will control accommodation and allow accurate assessment of the subject's visual status. These results will allow the Investigator to judge whether or not the contact lens BVP is acceptable.

Bailey Lovie chart

LogMAR visual acuity can also be measured on a card-based Bailey-Lovie chart. The use of this chart is covered in more detail in the relevant SOP[1]. In summary the differences are:

1. Unless specified the Bailey-Lovie chart is used at a testing distance of 3m as it is viewed directly.
2. The font used (5x5 sans-serif font)[2] is that defined in the British Standard: BS 4274.
3. If the Bailey-Lovie is used at 3m, then it should not be used as a target to determine over-refraction. Instead an alternative chart (e.g. Snellen) positioned at 6m should be used.

References

1. Eurolens Research Standard Operating Procedure. Assessment of visual performance using the Bailey-Lovie logMAR visual acuity test chart and procedures for carrying out an over-refraction.
2. BS 4274-1:2003. Visual acuity test types. Test charts for clinical determination of distance visual acuity – Specification.

Appendix A. Screen inclination calculation

To calculate chart inclination

$$\text{Tan (angle of chart inclination)} = \frac{\text{Subject's distance below chart}}{\text{Subject to chart distance (parallel to floor)}}$$

Room	1.015	1.014	1.013	1.012
Subject's distance below chart (eye to top of monitor) (cm)*	50	65	65	65
Subject to chart distance (parallel to floor) (cm)	600	605	610	600
Calculated chart inclination (degrees)	4.7	6.1	6.1	6.2

Table 2: Eurolens clinic room screen inclination.

* Subject with Eurolens ID 2023 of average UK male height (175cm, ONS data) was used

Appendix B. Example of chart settings (11 October 2017)

Clinic room	1.012	1.013	1.014	1.015	1.018
Monitor number	4	5	3	1	2
Chart distance (m)	6.0	6.1	6.05	6.0	6.1
LC grey	240	240	243	240	237

Table 3: Eurolens clinic room chart settings

All monitors calibrated were a BenQ G2255 displaying the chart at native resolution (1920x1080).

Appendix C. Revisions to chart software

2008

Initial clinic version of computer chart software

01/02/2013 v5

2013 version of chart software was rewritten for compatibility with Office 2011 and Mac OSX10.8. Contains the following amendments:

- Colours of the control box have been altered for better legibility with office 2011
- Chart letter display was updated for 16:9 monitors
- Letter size is calculated correctly for chart distance
- Low contrast letters contrast adjustable from chart control panel.

APPENDIX G: EUROLENS RESEARCH SOP 'EXAMINATION OF THE ANTERIOR SEGMENT USING SLIT LAMP BIOMICROSCOPY'

Eurolens Research

Clinical
Standard Operating Procedure

Examination of the anterior segment using slit lamp biomicroscopy

Carole Maldonado-Codina
Associate Director

First issued: v0; May 20, 2002
Reviewed (with changes): v2; June 26, 2009
Reviewed (no changes): v2; October 14, 2011
Reviewed (with changes): v3; March 4, 2014
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Title:	Examination of the anterior segment using slit lamp biomicroscopy
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Document author: Carole M-Codina Date: 2 Feb, 2016
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Document reviewed by: G Howarth Date: 2 feb 2016
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Research Optometrist

Document reviewed and approved by: Michelle Inwood Date: 2 Feb 2016
Michelle Inwood
Project Officer (Business Systems)

Document approved by: P Morgan Date: 2 Feb 2016
Philip Morgan
Director

Summary

The slit lamp biomicroscope is a high quality illuminating observation system which allows the external and internal ocular structures to be assessed in detail. The Efron Grading Scales for Contact Lens Complications[1] will be used to quantify most of the observations made. If an alternative grading scale is to be used this will be detailed in the study protocol.

Definitions

External ocular structures in this procedure refer to the following structures: conjunctiva, sclera, limbus and associated blood vessels, cornea, lids, lashes and tear film.

Internal ocular structures in this procedure refer to the anterior chamber.

Wratten 12 filter – A yellow filter which enhances the contrast of fluorescein staining when viewed using cobalt blue light.

Procedure

1. Using the recommended settings for slit width, magnification and filter, examine the external and internal ocular structures[2]. The following primary signs should be graded using the Efron Grading Scales: conjunctival redness, limbal redness, corneal neovascularisation, epithelial microcysts, corneal oedema and corneal infiltrates. The following secondary signs are also usually graded using the Efron Grading Scales: blepharitis and meibomian gland dysfunction. The number of mucin balls present are counted and recorded.
2. Instil sodium fluorescein (using a fluorescein ophthalmic strip wetted with saline) in both eyes and using cobalt blue light and a Wratten 12 filter or similar yellow filter, examine and grade the following: corneal and conjunctival staining. The location and 'type' of any staining is also usually recorded. Corneal staining type is usually divided into the following categories: no staining, toxicity, SEAL, foreign body/abrasion, inferior dehydration and non-specific.
3. The upper eyelid should then be everted and examined both with cobalt blue light (with the yellow filter in place) and with white light (no filter in place). The grading of upper palpebral conjunctivitis should then be made with the Efron Grading Scales.
4. If a soft contact lens needs to be applied after the examination, irrigate the eye with unpreserved sterile saline once the examination has been completed in order to remove excess sodium fluorescein.

Recording slit lamp findings

Grades for the appearance of the ocular structures are recorded and classified according to Table 1 using Efron Grading Scales. Grades are scored to the nearest 0.1 in the best judgment of the investigator, with the exception of mucin balls where the number is counted. Location of staining is categorised as either superior, inferior, central, nasal or temporal.

Classification	Primary signs	Secondary signs
Signs	Conjunctival redness Limbal redness Corneal neovascularisation Epithelial microcysts Corneal oedema Corneal infiltrates Corneal staining Location of staining Conjunctival staining Papillary conjunctivitis	Blepharitis Meibomian gland dysfunction Mucin balls
Scale	Efron Grading Scales (scored to nearest 0.1)	Efron Grading Scales (scored to nearest 0.1) (except mucin balls, where the number is recorded).

Table 1: Biomicroscopic signs.

References

1. Efron Grading Scales for Contact Lens Complications devised by Nathan Efron (2000 Millennium edition).
2. Morris J (2013). Slit lamp biomicroscopy. Optometry in Practice: 14 (3): 85-96.

APPENDIX H: CRITERIA FOR ASSESSMENT OF OPTIMAL/NON-OPTIMAL LENS APPLICATION AND EYEGENIE TECHNIQUE.

During Visit 1, the investigator is required to assign a subject as having either (i) optimal lens application technique, or (ii) non-optimal lens application technique. Below is guidance on this criteria to aid the investigator.

Criteria for assigning a subject as having either optimal or non-optimal lens application technique:

In Visit 1, each subject will have a maximum of three attempts to successfully apply each of the study contact lenses. If they achieve this they will be classified as having optimal lens handling technique, otherwise they will be classified as having non-optimal lens handling technique (and thus discontinued from the study).

During Visit 1, the investigator is required to assign a subject as having either (i) optimal Eyegenie technique, or (ii) non-optimal Eyegenie technique. Below is guidance on this criteria to aid the investigator.

Criteria for assigning a subject as having either optimal or non-optimal Eyegenie technique:

In Visit 1, each subject will have a maximum of three attempts, to successfully place the Eyegenie onto the lid margins and retract the eyelids. If they achieve this on both eyes they will be classified as having optimal Eyegenie technique, otherwise they will be classified as having non-optimal Eyegenie technique (and thus discontinued from the study).

APPENDIX I: IMAGE CAPTURE SYSTEM AND PROCEDURES

Specification of the image capture system

The imaging system is based on a digital camera (Canon 6D) equipped with a 100mm macro lens (Canon EF 100mm f2.8L Macro lens) and macro flash unit (Canon MT-24). The dual flash units each have a custom filter mount to allow an optical band filter to be mounted (Edmunds Optical OD6 472nm / 30nm band- pass filter). A band filter is also mounted on the front of the macro optics (Edmunds Optical OD6 502nm / 30nm band- pass filter). The camera is mounted on an ophthalmic instrument base to allow 3-axis movement. To allow focusing an LED lamp (Thorlabs LIU470A) is used, which is also fitted with a band filter (Edmunds Optical OD6 472nm / 30nm band- pass filter).

The camera settings used during image capture detailed below:

ISO	1600
Lens aperture	f20
Exposure	1/15 seconds
Flash power setting	1/1
Macro lens imaging ratio	1:1

Study visit image capture

At all study visits, photographs will captured using a custom imaging system, to characterize the fluorescence at the ocular surface. At visit 1, images will be captured to quantify baseline fluorescence during wear of each of the study lens types (i.e. fluorescence of the ocular surface and study lens combined). At visit 2-5, a baseline image will be captured prior to lens/microsphere application (i.e. fluorescence from the ocular surface only). In the right eye, microsphere will be applied to the ocular surface as detailed in Appendix E and according to the randomization schedule. A series of digital images will be captured over a 30-minute period (every minute for the first 10 minutes and then every 5 minutes for the next 20 minutes). In the left eye, the microsphere suspension will be applied as detailed in Appendix E and according to the randomization schedule. A series of digital images will then be captured every minute for 10 minutes.

Image capture procedure:

1) The investigator will confirm that the camera settings are as detailed above.
2) Subject instructed to place chin on chinrest and forehead against the headrest.
3) The subject is instructed to look directly into the centre of the camera optics.
4) The subject is instructed to use the Eyegenie lid retractor to allow the entire contact lens region (or equivalent region when no lens is worn) to be imaged.
5) The investigator observes the live camera feed via a wall mounted display, centers the cornea in the frame and focuses the image.
6) An image is then captured and reviewed by the investigator; if the image is unacceptably aligned or blurred another image will be captured.
7) Following image capture the subject is instructed to cease use of the Eyegenie and sit back from the instrument.

APPENDIX J: BLINK ANALYSIS

Blinking characteristics will be captured using an infra-red camera (FLIR Grasshopper 3 camera) and infra-red LED illumination (Thorlabs LIU780A). During video capture the subject will be directed to view a wildlife video on an Ipad at a working distance of approximately 1 meter. The infrared video will be captured for 3 minutes at 500 frames per second.

Blink analysis procedures:

1) The investigator will use disinfecting wipes to clean the chin/headrest.
2) The investigator will adjust the table and chin rest height to suit the subject.
3) The subject will be asked to sit forward and place their chin on the chinrest.
4) The camera will be adjusted to centre the subject's eye in the monitor.
5) A wildlife video will be started on the Ipad and video capture will begin.
6) The recording will be captured at 500 frames per second for 3 minutes.
7) The video will then be saved.
8) Subsequent video analysis will record the blink rate (blinks per minute) over the 3-minute period.

APPENDIX K: VAS SCALE

Site # [redacted] Subject # [ ][ ][ ]

VISIT 2

How would you rate your current contact lenses with regard to the following? Think about each the eye and place a vertical line through each scale at the point between the two extremes (scale of 0-100mm) you consider to be the most appropriate position.

Q1. Overall comfort - Please rate how comfortable each eye is overall on the scale below:

How would you rate your current contact lenses with regard to the following? Think about the lens and place a vertical line through each scale at the point between the two extremes (scale of 0-100mm) you consider to be the most appropriate position.

Q2. Comfort - Please rate the comfort of your lenses overall on the scale below:

Subject Initials: _____ **Today's Date:** _____

Investigator Use Only

OS Value **OD Value**

Completed By (initials): _____ **Date:** ____/____/____
Day / Month / Year

PROTOCOL COMPLIANCE INVESTIGATOR(S) SIGNATURE PAGE

Protocol Number and Title: CR-6291 Influence of Lens Design on Particulate Exchange in the Post-lens Tear Film

Version and Date: 1.0 06 September 2018

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

I agree to conduct this study according to ISO 14155,[1] GCP and ICH guidelines,[2] the Declaration of Helsinki,[3] United States (US) Code of Federal Regulations (CFR),[7] and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. The Principal Investigator is responsible for ensuring that all clinical site personnel, including Sub-Investigators adhere to all ICH[2] regulations and GCP guidelines regarding clinical trials during and after study completion.

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

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

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

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

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

Principal Investigator:

_____ _____

Signature Date

_____

Name and Professional Position (Printed)

Institution/Site: _____

Institution/Site Name

_____

Institution/Site Address