Alcon

Title:

Clinical Comparison of Two Daily Wear Frequent Replacement Silicone Hydrogel Soft Contact Lenses

Protocol Number:	CLY935-C020 / NCT04532099
Sponsor Name and Address:	Alcon Research, LLC 6201 South Freeway Fort Worth, Texas 76134-2099
Test Product(s):	LID018869

Investigator Agreement:

- I have read the clinical study described herein, recognize its confidentiality, and agree to conduct the described trial in compliance with Good Clinical Practice (GCP), the ethical principles contained within the Declaration of Helsinki, this protocol, all applicable regulatory authority regulations, and conditions of approval imposed by the reviewing IRB or regulatory authority.
- I will supervise all testing of the device involving human subjects and ensure that the requirements relating to obtaining informed consent and IRB review and approval are met in accordance with applicable local and governmental regulations.
- I have read and understand the appropriate use of the investigational product(s) as described in the protocol, current Investigator's Brochure, product information, or other sources provided by the sponsor.
- I understand the potential risks and side effects of the investigational product(s).
- I agree to maintain adequate and accurate records in accordance with government regulations and to make those records available for inspection.
- I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements of the sponsor and government agencies.
- I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed of their obligations in meeting the above commitments.

Have you ever been disqualified as an investigator by any Regulatory Authority? ☐ No ☐ Yes
Have you ever been involved in a study or other research that was terminated? ☐ No ☐ Yes If yes, please explain here:

Principal Investigator:

Signature Date

Name and professional position:

Address:

1 PROTOCOL SYNOPSIS

Trial Sponsor	Alcon Research, LLC 6201 South Freeway Fort Worth, Texas 76134-2099
Name of Test Product(s)	LID018869
Name of Control Product(s)	Control Product 1 (Part A): ACUVUE OASYS® with HYDRACLEAR® PLUS (AOHP) Control Product 2 (Part B): CooperVision® Biofinity® (Biofinity)
Title of Trial	Clinical Comparison of Two Daily Wear Frequent Replacement Silicone Hydrogel Soft Contact Lenses
Protocol Number	CLY935-C020
Number of Sites Country	~4 US
Planned Duration of Exposure – Part A	~60 days total duration (test and control): Test Product: ~30 days Control Product 1: ~ 30 days (2x ~15 days)
Planned Duration of Exposure – Part B	~30 days total duration (control only) Control Product 2: ~ 30 days
Number of Subjects – Part A	Target to complete: 60 (~30 per each parallel group) Planned to enroll: ~66
Number of Subjects – Part B	Target to complete: 60 (~ 30 per each parallel group) Planned to enroll: ~66
Study Population	Volunteer subjects aged 18 or over who are habitual spherical [redacted] soft contact lens wearers, have at least 3 months of contact lens wearing experience, and who wear their habitual lenses at least 5 days per week and at least 10 hours per day. [redacted]

	[redacted]
Objective(s)	The primary objective of this study is to evaluate the overall performance of an investigational silicone hydrogel lens when compared to AOHP. [redacted]
Endpoints	Primary Effectiveness • Distance VA (logMAR) with study lenses [redacted] Safety • AEs • Biomicroscopy findings • Device deficiencies
Assessments	Effectiveness • Distance VA (logMAR) with study lenses • Distance VA (Snellen) habitual correction • Manifest refraction • BCVA (Snellen distance with manifest refraction) [redacted]

<table>
<tr><td></td><td colspan="2">• [redacted]

Safety
• AEs
• Biomicroscopy
• Device deficiencies</td></tr>
<tr><td rowspan="3">Study Design – Part A</td><td>☒ Prospective
☐ Single group
☒ Parallel group
☒ Crossover
☐ Other</td><td>☐ Single-masked (trial subject)
☐ Single-masked (Investigator)
☒ Double-masked
☐ Open-label
☐ Other</td></tr>
<tr><td>☐ Contralateral
☒ Bilateral
☐ Monocular lens wear</td><td>☒ Randomized</td></tr>
<tr><td colspan="2">Randomization scheme [redacted]
Sequence 1: LID018869 → AOHP
Sequence 2: AOHP → LID018869</td></tr>
<tr><td rowspan="3">Study Design – Part B</td><td>☒ Prospective
☒ Single group
[redacted]
☐ Crossover
☐ Other</td><td>☒ Single-masked (trial subject)
☐ Single-masked (Investigator)
☐ Double-masked
☐ Open-label
☐ Other</td></tr>
<tr><td>☐ Contralateral
☒ Bilateral
☐ Monocular lens wear</td><td>☐ Randomized</td></tr>
</table>

Test Product Details	Primary component/material	Lehfilcon A
	Manufacturer	Alcon
	LID Number	LID018869
	[redacted]	[redacted]
Control Product 1 Details	Primary component/material	Senofilcon A
	Manufacturer	Johnson & Johnson
	LID Number	N/A
	Product Name	Acuvue Oasys with Hydraclear Plus (AOHP)
	[redacted]	[redacted]
Control Product 2 Details	Primary component/material	Comfilcon A
	Manufacturer	CooperVision
	LID Number	N/A
	Product Name	Biofinity
	[redacted]	[redacted]
Inclusion Criteria	1. Subject must be at least 18 years of age. 2. Subject must be able to understand and must sign an ICF that has been approved by an IRB. 3. Successful wear of spherical contact lenses in both eyes for a minimum of 5 days per week and 10 hours per day during the past 3 months. [redacted] 6. Subject must possess spectacles and be willing to wear habitual spectacles for vision correction when study lenses are not worn, as needed. [redacted]	
Exclusion Criteria	1. Any anterior segment infection, inflammation, or abnormality or disease (including systemic) that	

	contraindicates contact lens wear, as determined by the Investigator. 2. Any use of systemic or ocular medications for which contact lens wear could be contraindicated, as determined by the Investigator. 3. History of refractive surgery or plan to have refractive surgery during the study or irregular cornea in either eye. [redacted] 6. Current or history of pathologically dry eye in either eye that, in the opinion of the Investigator, would preclude contact lens wear. [redacted] 10. Wearing habitual contact lenses in an extended wear modality (routinely sleeping in lenses for at least 1 night per week) over the last 3 months prior to enrollment. [redacted] 15. Current habitual wearers of AOHP.€

	[redacted] 17. Current habitual wearer of Biofinity family of contact lenses (comfilcon A). [redacted]
Associated Materials	• CLEAR CARE® contact lens solution [redacted]

Table 1-1 Schedule of Study Procedures and Assessments – Part A

Procedure/ Assessment	PRESCREENING	LENS 1			LENS 2			
		Visit 1 Screen/ Baseline/ Dispense Lens 1	**Visit 2** Day 15 Follow-up Lens 1 [redacted]	**Visit 3** Day 30 Follow-up Lens 1 [redacted] Dispense Lens 2		**Visit 4** Day 15 Follow-up Lens 2 [redacted]	**Visit 5** Day 30 Follow-up Lens 2 /Exit^ [redacted]	**USV**
				Follow-up Lens 1	Dispense Lens 2			
Informed Consent		X						
Demographics		X						
Medical History*		X	X	X		X	X	X
Concomitant Medications*		X	X	X		X	X	X
Inclusion/ Exclusion		X						
Habitual (lens brand, lens power*, lens care)		X						
VA w/ habitual correction* (OD, OS, Snellen distance)		X					X	(X)
Manifest Refraction and BCVA with manifest refraction* (OD, OS, Snellen distance)		X	(X)	(X)		(X)	(X)	(X)
Biomicroscopy		X	X	X		X	X	X
[redacted]	[redacted]	[redacted]						
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Randomization and record lens power*		X						
Dispense study lenses		X	(X)$^{\Omega}$		X	(X)$^{\Omega}$		(X)
VA w/ study lenses (OD, OS, logMAR distance)		X	X	X	X	X	X	(X)
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Procedure/ Assessment	PRESCREENING	LENS 1			LENS 2			
		Visit 1 Screen/ Baseline/ Dispense Lens 1	**Visit 2** Day 15 Follow-up Lens 1	**Visit 3** Day 30 Follow-up Lens 1 [redacted] Dispense Lens 2		**Visit 4** Day 15 Follow-up Lens 2	**Visit 5** Day 30 Follow-up Lens 2 /Exit^	**USV**
				Follow-up Lens 1	Dispense Lens 2			
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
AEs§		X	X	X	X	X	X	X
Device deficiencies		X	X	X	X	X	X	X
Exit Form		(X)	(X)	(X)	(X)	(X)	X	(X)

USV = Unscheduled visit

[redacted]

Table 1-2 Schedule of Study Procedures and Assessments – Part B

Procedure/ Assessment	PRESCREENING	Visit 1 Screen/ Baseline/ Dispense Lens 1	Visit 2 Day 15 Follow-up Lens 1 [redacted]	Visit 3 Day 30 Follow-up Lens 1/Exit^ [redacted]	USV
Informed Consent		X			
Demographics		X			
Medical History*		X	X	X	X
Concomitant Medications*		X	X	X	X
Inclusion/ Exclusion		X			
[redacted]		[redacted]			
Habitual (lens brand, lens power*, lens care)		X			
VA w/ habitual correction* (OD, OS, Snellen distance)		X		X	(X)
Manifest Refraction and BCVA with manifest refraction* (OD, OS, Snellen distance)		X	(X)	(X)	(X)
Biomicroscopy		X	X	X	X
[redacted]	[redacted]	[redacted]			
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
Record lens power*		X			
Dispense study lenses		X	(X)		(X)
VA w/ study lenses (OD, OS, logMAR distance)		X	X	X	(X)
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]			[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
Collect worn lenses*		(X)	(X)	X	(X)
AEs§		X	X	X	X
Device deficiencies		X	X	X	X

Procedure/ Assessment	PRESCREENING	Visit 1 Screen/ Baseline/ Dispense Lens 1	Visit 2 Day 15 Follow-up Lens 1 [redacted]	Visit 3 Day 30 Follow-up Lens 1/Exit^ [redacted]	USV
Exit Form		(X)	(X)	(X)	(X)

USV = Unscheduled visit

[redacted]

1.1 Abbreviations

Abbreviation	Definition
ADE	Adverse device effect
AE	Adverse event
AOHP	ACUVUE OASYS with HYDRACLEAR PLUS
BCVA	Best corrected visual acuity
Biofinity	CooperVision Biofinity
CFR	Code of Federal Regulations
D	Diopter
D/C	Discontinue
eCRF	Electronic case report form
EDC	Electronic data capture
FDA	US Food and Drug Administration
GCP	Good Clinical Practice
ICF	Informed consent form
IP	Investigational product
IRB	Institutional review board
ISO	International Organization for Standardization
LID	Lens identification
LogMAR	Logarithm of the minimum angle of resolution
[redacted]	[redacted]
[redacted]	[redacted]
MR	Manifest refraction
N/A	Not applicable
OD	Right eye
OS	Left eye
OU	Both eyes
SAE	Serious adverse event
SADE	Serious adverse device effect
US	United States
USV	Unscheduled visit
VA	Visual acuity
[redacted]	[redacted]

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3 INTRODUCTION

3.1 Study Rationale and Purpose

The new contact lens in development is intended for the optical correction of refractive ametropia in persons with non-diseased eyes. The purpose of this study is to evaluate performance of two commercially available daily wear frequent replacement silicone hydrogel soft contact lenses as compared to investigational test product (LID018869) to obtain on-eye performance data [redacted]

The primary endpoint was selected to address the primary objective of the study. Procedures for measurement of these endpoints were selected based on common practice for these assessments. [redacted]

3.2 Trial Objective

The primary objective of this study is to evaluate the overall performance of an investigational silicone hydrogel lens when compared to AOHP. [redacted]

3.3 Risks and Benefits

Contact lenses may offer improved peripheral vision and the convenience of not wearing spectacles. Material properties and design characteristics of the contact lens in development are features consistent with successful contact lens wear.

[redacted]

[redacted]

AOHP contact lenses are commercially available for daily wear use under a biweekly replacement schedule; Biofinity contact lenses are commercially available for daily wear use under a monthly replacement schedule; further details on any known potential risks and benefits can be found in the package insert. Refer to Appendix 13.1 and Appendix 13.2.

The site personnel will educate subjects on proper hygiene and lens handling, and compliance with the use of contact lenses according to the protocol. Subjects should be instructed not to wear contact lenses while sleeping or swimming. The site personnel will also advise the subjects to remove contact lenses and return for prompt follow-up of symptoms, such as ocular discomfort, foreign body sensation, excessive tearing, vision changes, or hyperemia.

3.4 Subject Population

The study population for Part A and Part B each includes approximately 66 volunteer subjects to be enrolled at approximately 4 sites, with approximately 16-18 subjects enrolled per site. The study population will consist of subjects with normal eyes (other than the need for optical correction for myopia), who are adapted, existing wearers of soft contact lenses in both eyes. [redacted]

[redacted]

[redacted]

3.5 Outline of Study

Part A of this study will be a multi-site, prospective, randomized, double-masked, [redacted] crossover study comparing 2 contact lenses. The expected duration of subject participation in this part is approximately 8 weeks, with 5 scheduled visits. [redacted].

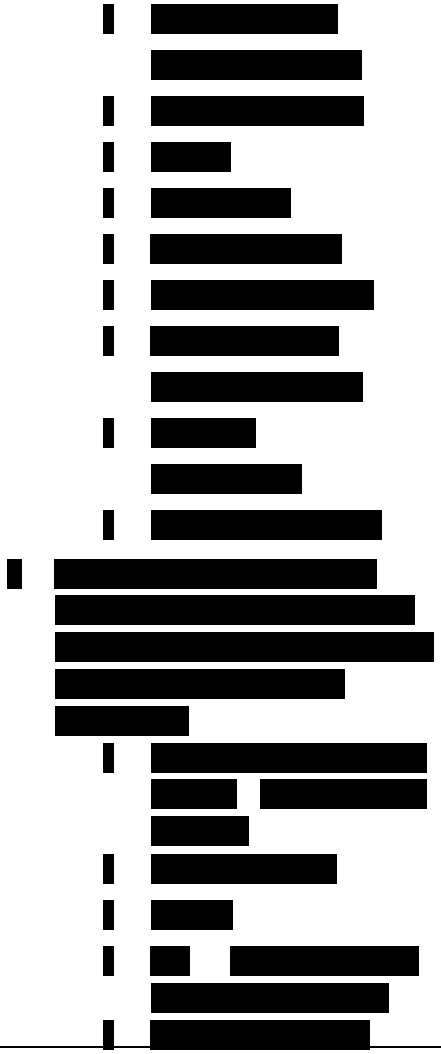
Part B will start after Part A has completed. Part B of this study will be a multi-site, prospective, single-arm, single-masked, [redacted]) study with 1 contact lens. The expected duration of subject participation in Part B of the study is approximately 4 weeks, with 3 scheduled visits. [redacted]

4 TREATMENTS ADMINISTERED

In Part A, subjects will [redacted] receive treatment (lens) in a crossover sequence: Test product then Control product 1, or Control product 1 then Test product. In Part B, subjects will only receive one pair of Control product 2 lenses.

4.1 Identity of Study Treatments – Part A

DESCRIPTION OF TEST AND CONTROL PRODUCTS		
	Test Product	Control Product 1
LID Number	LID018869	N/A
Lens identified in randomization system as:	LID018869	AOHP
Material	Lehfilcon A	Senofilcon A
Water Content	[redacted]	38%
Base Curve (mm)	[redacted]	8.4 mm, 8.8 mm
Diameter (mm)	[redacted]	14.0 mm
[redacted]	[redacted]	[redacted]
Packaging, Labeling, and Supply	• Blister foil pack [redacted]	• Blister foil pack • Commercial foil • Provided in commercial packaging • Lenses should be

DESCRIPTION OF TEST AND CONTROL PRODUCTS		
	Test Product	Control Product 1
		stored at room temperature.
	• Lenses should be stored at room temperature.	
Usage	• Wear: ○ Daily Wear	• Wear: ○ Bilateral

DESCRIPTION OF TEST AND CONTROL PRODUCTS		
	Test Product	Control Product 1
	• [redacted]	[redacted]
	[redacted] • Exposure: ~30 days for each lens assignment. Subjects are to wear the lenses every day, at least 10 hours per day. [redacted] • Lens Care: Cleaned and disinfected with CLEAR CARE contact lens solution	
	[redacted]	
[redacted]	[redacted]	[redacted]

4.2 Identity of Study Treatments – Part B

DESCRIPTION OF CONTROL PRODUCT	
	Control Product 2
LID Number	N/A
Lens identified in	Biofinity

DESCRIPTION OF CONTROL PRODUCT	
	Control Product 2
randomization system as:	
Material	Comfilcon A
Water Content	48%
Base Curve (mm)	8.6 mm
Diameter (mm)	14.0 mm
[redacted]	[redacted]
Packaging, Labeling, and Supply	• Blister foil pack • Commercial foil • Provided in commercial packaging • Lenses should be stored at room temperature.
Usage	• Wear: o Bilateral
	[redacted]
	[redacted] • Exposure: ~30 days. Subjects are to wear the lenses every day, at least 10 hours per day. [redacted] • Lens Care: Cleaned and disinfected with CLEAR CARE contact lens solution.
	[redacted]
[redacted]	[redacted]

4.3 Accountability Procedures

[redacted]

Designated study staff will provide the study lenses to the subjects in accordance with their randomization schedule. [redacted]

[redacted]

It is the Investigator's responsibility to ensure that:

- All study products are accounted for and not used in any unauthorized manner
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

5 STUDY PROCEDURES AND ASSESSMENTS

5.1 Visits and Examinations – Part A

[redacted]

[redacted]	[redacted]

5.1.2 Visit 1 (Screen/Baseline/Lens 1: Dispense)

1	Explain the purpose and nature of the study, and have the subject read, sign, and date the IRB-approved informed consent document. Additionally, have the individual obtaining consent from the subject and a witness, if applicable, sign and date the informed consent document. Provide a photocopy of the signed document to the subject and place the original signed document in the subject's chart. After signing the ICF, a subject will be assigned a subject number by the EDC system. A signed informed consent document defines the point of enrollment.
2	Obtain demographic information and medical history, including information on all medications used within the past 30 days. [redacted]
3	Record habitual lens information (brand, power) and lens care information (brand).
4	Perform VA with habitual correction (OD, OS, Snellen distance).
[redacted]	[redacted]
6	Perform manifest refraction and BCVA with manifest refraction (OD, OS, Snellen distance) *Note: Distance BCVA must be 20/25 or better in each eye for the subject to qualify for the study.*
7	Perform slit-lamp biomicroscopy (without contact lenses) [redacted]
8	Review inclusion/exclusion criteria to determine if the subject qualifies to be randomized into the study. If subject qualifies, randomize in EDC and record lens power. If subject does not qualify, exit the subject from the study as a screen failure.

9	Based upon the randomized lens sequence assignment, have the subject insert the appropriate Lens 1 study lenses, being careful to maintain the correct OD and OS lens assignments.
10	Evaluate the study lenses by performing: • VA with study lenses (logMAR OD and OS, at distance)
12	Assess and record any AEs and device deficiencies reported or observed during the study visit.
13	Dispense study lens case and lens care solutions (CLEAR CARE contact lens solution).

14	Schedule Visit 2 to take place 15 [redacted] days after Visit 1. [redacted]
[redacted]	[redacted]

5.1.3 Visit 2 (Lens 1: Day 15 Follow-up) – [redacted]

1	Obtain information on any changes in medical health and/or the use of concomitant medications.
2	Record any device deficiencies or AEs, including those associated with changes in concomitant medication dosing, which are observed or reported since the previous visit. Collect any ADE/AE/Device Deficiency lenses [redacted]
[redacted]	[redacted]
[redacted]	[redacted]
5	Evaluate the study lenses by performing: VA with study lenses (logMAR OD and OS, at distance)
6	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
9	Perform slit-lamp biomicroscopy
10	If warranted, perform Manifest Refraction and BCVA with manifest refraction (OD, OS, Snellen distance)
11	Assess and record any AEs and device deficiencies reported or observed during the study visit. [redacted]
[redacted]	[redacted]
13	Schedule Visit 3 to take place 15 [redacted] days after Visit 2. [redacted]
[redacted]	[redacted]

5.1.4 Visit 3 (Lens 1: Day 30 Follow-up; Lens 2: Dispense) – [redacted]

1	Obtain information on any changes in medical health and/or the use of concomitant medications.

2	Record any device deficiencies or AEs, including those associated with changes in concomitant medication dosing, which are observed or reported since the previous visit(s). Collect any ADE/AE/Device Deficiency lenses
[redacted]	[redacted].
[redacted]	[redacted]
5	Evaluate the study lenses (Lens1) by performing: VA with study lenses (logMAR OD and OS, at distance)
[redacted]	[redacted]
[redacted]	[redacted]
8	Perform slit-lamp biomicroscopy (without contact lenses) [redacted]
9	If warranted, perform Manifest Refraction and BCVA with manifest refraction (OD, OS, Snellen distance)
10	Based upon the randomized lens sequence, have the subject insert the appropriate study Lens 2, being careful to maintain the correct OD and OS lens assignments. [redacted]

11	Evaluate the study lenses (Lens 2) by performing: • VA with study lenses (logMAR OD and OS, at distance) [redacted]
[redacted]	[redacted]
13	Assess and record any AEs and device deficiencies reported or observed during the study visit. [redacted]
14	Dispense study lens case and lens care solutions (CLEAR CARE contact lens solution) [redacted]
15	Schedule Visit 4 to take place 15 [redacted] days after Visit 3. [redacted]
[redacted]	[redacted]

5.1.5 Visit 4 (Lens 2: Day 15 Follow-up) – [redacted]

1	Obtain information on any changes in medical health and/or the use of concomitant medications.
2	Record any device deficiencies or AEs including those associated with changes in concomitant medication dosing, which are observed or reported since the previous visit(s). Collect any ADE/AE/Device Deficiency lenses[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
5	Evaluate the study lenses by performing: • VA with study lenses (logMAR OD and OS, at distance)
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
9	Perform slit-lamp biomicroscopy
10	If warranted, perform Manifest Refraction and BCVA with manifest refraction (OD, OS, Snellen distance)
11	Assess and record any AEs and device deficiencies reported or observed during the study visit. [redacted]
12	Review and dispense the following with the subject: [redacted]

13	Schedule Visit 5 to take place 15 days after Visit 4.

5.1.6 Visit 5 (Lens 2: Day 30 Follow-up/Exit) –

1	Obtain information on any changes in medical health and/or the use of concomitant medications.
2	Record any device deficiencies or AEs including those associated with changes in concomitant medication dosing, which are observed or reported since the previous visit.
5	Evaluate the study lenses (Lens 2) by performing: • VA with study lenses (logMAR OD and OS, at distance)

9	Perform slit-lamp biomicroscopy (without contact lenses) [redacted]
10	If warranted, perform Manifest Refraction and BCVA with manifest refraction (OD, OS, Snellen distance).
11	Perform VA with habitual correction (OD, OS, Snellen distance). [redacted]
12	Assess and record any AEs and device deficiencies reported or observed during the study visit. [redacted]
13	Exit the subject from the Part A of the study.

5.1.7 Unscheduled Visit

1	Obtain information on any changes in medical health and/or the use of concomitant medications.
2	Record any device deficiencies or AEs including those associated with changes in concomitant medication dosing, which are observed or reported since the previous visit(s). Collect any ADE/AE/Device Deficiency lenses [redacted]

3	Perform slit-lamp biomicroscopy (without contact lenses) [redacted]: [redacted]
	[redacted]
[redacted]	[redacted]
5	Perform VA with habitual correction (OD, OS, Snellen distance).
6	Evaluate the study lenses by performing: • VA with study lenses (logMAR OD and OS, at distance)
7	If applicable, perform manifest refraction and BCVA distance with manifest refraction (OD, OS, Snellen)
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
12	Assess and record any AEs and device deficiencies reported or observed during the study visit. [redacted]
[redacted]	[redacted]

5.2 Visits and Examinations – Part B

[redacted]

[redacted]	[redacted]

5.2.2 Visit 1 (Screen/Baseline/Dispense Lens 1)

1	Explain the purpose and nature of the study, and have the subject read, sign, and date the IRB-approved informed consent document. Additionally, have the individual obtaining consent from the subject and a witness, if applicable, sign and date the informed consent document. Provide a photocopy of the signed document to the subject and place the original signed document in the subject's chart. After signing the ICF, a subject will be assigned a subject number by the EDC system. A signed informed consent document defines the point of enrollment.
2	Obtain demographic information and medical history, including information on all medications used within the past 30 days [redacted]
3	Record habitual lens information (brand, power) and lens care information (brand).
4	Perform VA with habitual correction (OD, OS, Snellen distance).
[redacted]	[redacted]
[redacted]	[redacted]
7	Perform manifest refraction and BCVA with manifest refraction (OD, OS, Snellen distance) [redacted]

8	Perform slit-lamp biomicroscopy (without contact lenses) [redacted]
9	Review inclusion/exclusion criteria to determine if the subject qualifies to be in the study. If subject qualifies, record lens power to be dispensed. [redacted]
10	Have the subject insert Lens 1, being careful to maintain the correct OD and OS lens assignments. [redacted]
11	Evaluate the study lenses by performing: • VA with study lenses (logMAR OD and OS, at distance) [redacted]
[redacted]	[redacted]
13	Assess and record any AEs and device deficiencies reported or observed during the study visit. [redacted]

14	Dispense study lens case and lens care solutions (CLEAR CARE contact lens solution).
15	Schedule Visit 2 to take place 15 days after Visit 1.

5.2.3 Visit 2 (Lens 1: Day 15 Follow-up) –

1	Obtain information on any changes in medical health and/or the use of concomitant medications.
2	Record any device deficiencies or AEs, including those associated with changes in concomitant medication dosing, which are observed or reported since the previous visit. Collect any ADE/AE/Device Deficiency lenses
5	Evaluate the study lenses by performing: VA with study lenses (logMAR OD and OS, at distance)

6	[redacted]
[redacted]	[redacted]
8	Perform slit-lamp biomicroscopy
9	If warranted, perform Manifest Refraction and BCVA with manifest refraction (OD, OS, Snellen distance)
10	Assess and record any AEs and device deficiencies reported or observed during the study visit. [redacted]
[redacted]	[redacted]
12	Schedule Visit 3 to take place 15 [redacted] days after Visit 2. [redacted]
13	[redacted]

5.2.4 Visit 3 (Lens 1: Day 30 Follow-up/Exit) – [15 [redacted] days after Visit 2]

1	Obtain information on any changes in medical health and/or the use of concomitant medications.
2	Record any device deficiencies or AEs, including those associated with changes in concomitant medication dosing, which are observed or reported since the previous visit(s). Collect any ADE/AE/Device Deficiency lenses [redacted]
3	[redacted]
4	[redacted]
5	Evaluate the study lenses by performing: VA with study lenses (logMAR OD and OS, at distance)
6	[redacted]
7	Have the subject remove Lens 1 and collect the worn lenses. Record the study lens removal time on day of study visit.
8	Perform slit-lamp biomicroscopy (without contact lenses) [redacted]
9	If warranted, perform Manifest Refraction and BCVA with manifest refraction (OD, OS, Snellen distance)
10	Perform VA with habitual correction (OD, OS, Snellen distance). *Note: If this VA with habitual correction shows a decrease of 2 lines or more versus Visit 1 baseline VA with habitual correction, then BCVA with MR is required to confirm a potential loss in VA for AE reporting requirements (see Section 7.3 Procedures for Recording and Reporting).*

11	Assess and record any AEs and device deficiencies reported or observed during the study visit. [redacted]
12	Exit the subject from Part B of the study.

5.2.5 Unscheduled Visit

1	Obtain information on any changes in medical health and/or the use of concomitant medications.
2	Record any device deficiencies or AEs including those associated with changes in concomitant medication dosing, which are observed or reported since the previous visit(s). Collect any ADE/AE/Device Deficiency lenses [redacted]
3	Perform slit-lamp biomicroscopy (without contact lenses) [redacted]: [redacted]
	The following are to be performed if applicable in the view of the Investigator
[redacted]	[redacted]
5	Perform VA with habitual correction (OD, OS, Snellen distance).
6	Evaluate the study lenses by performing: • VA with study lenses (logMAR OD and OS, at distance)
7	If applicable, perform manifest refraction and BCVA distance with manifest refraction (OD, OS, Snellen)
[redacted]	[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
11	Assess and record any AEs and device deficiencies reported or observed during the study visit. [redacted]
[redacted]	[redacted]

5.3 Unscheduled Visits

Any visit that occurs between regularly scheduled visits is an Unscheduled Visit. If [redacted] During all unscheduled visits, the Investigator must conduct the following procedures:

- Collect AE and Device Deficiency information
- Assess and record changes in medical condition or concomitant medication
- Assess and record VAs
- Perform biomicroscopy (assessments with or without lenses, as possible)

In addition, all procedures for Visit 5 (Follow-up/Exit) should be completed (as possible).The Investigator may perform additional procedures for proper diagnosis and treatment of the subject. The Investigator must document this information in the subject's case history source documents.

If during an Unscheduled Visit the subject is discontinuing the study lenses or discontinuing from the study, the Investigator must conduct Exit procedures according to Table 1-1: Schedule of Study Procedures and Assessments, as possible.

5.4 Discontinued Subjects

Discontinued subjects are those who withdraw or are withdrawn from the study after signing the informed consent, including screen failures. Subjects may discontinue from the study at any time for any reason. Subjects may also be discontinued from the study at any time if, in the opinion of the Investigator, their continued participation poses a risk to their health. Discontinued subjects will not be replaced [redacted]

[redacted]

5.5 Clinical Study Termination

The Study Sponsor reserves the right to close the investigational site or terminate the study in its entirety at any time, for reasonable cause.

[redacted]

[redacted]

6 ANALYSIS PLAN

Part A and Part B will be summarized and presented separately.

Continuous variables will be summarized using the number of observations, mean, standard deviation, median, minimum, and maximum. Categorical variables will be summarized with counts and percentages from each category.

Any deviations to this analysis plan will be updated during the course of the study as part of a protocol amendment or will be detailed in the clinical study report.

6.1 Subject Evaluability

The final subject evaluability for Part A will be determined prior to breaking the code for masked treatment (lens) sequence assignment and locking the respective subject data, based on the Deviations and Evaluability Plan (DEP).

Similarly, final subject evaluability for Part B will be determined prior to locking the database, based on the DEP.

6.2 Analysis Data Sets

6.2.1 Safety Analysis Set

Safety analyses will be conducted using the safety analysis set on a treatment-emergent basis. As such, the safety analysis set will include all subjects/eyes exposed to any study lenses evaluated in this study. For treatment-emergent safety analyses, subjects/eyes will be categorized under the actual study lenses exposed.

6.3 Demographic and Baseline Characteristics

Demographic information (age, sex, ethnicity, race) will be summarized on the Safety Analysis Set. Baseline data pertaining to habitual lens (lens brand, lens care brand) [redacted] will be summarized on the Safety Analysis Set as well.

6.4 Effectiveness Analyses

This study defines one primary endpoint [redacted]. The Safety Analysis Set will be used for all effectiveness analyses.

6.4.1 Primary Effectiveness

The primary objective of this study is to evaluate the overall performance of an investigational silicone hydrogel lens when compared to AOHP. The primary endpoint is distance VA with study lenses, collected in logMAR, for each eye.

6.4.1.1 Statistical Hypotheses

No inferences are to be made on the primary effectiveness endpoint; therefore, no hypotheses are formulated.

6.4.1.2 Analysis Methods

Descriptive statistics will be presented.

[redacted]

[redacted]

6.6 Handling of Missing Data

All data obtained in evaluable subjects/eyes will be included in the analysis. No imputation for missing values will be carried out for the primary analysis.

6.7 Multiplicity

No multiplicity adjustment needs to be considered for the effectiveness endpoints since no formal hypothesis testing will be conducted.

6.8 Safety Analysis

The safety endpoints for this study are AEs, biomicroscopy findings, and device deficiencies.

All AEs occurring from the time a subject signs informed consent to study exit will be accounted for in the reporting. Descriptive summaries (counts and percentages) for ocular and nonocular AEs will be presented by Medical Dictionary for Regulatory Activities Preferred Terms. AEs leading to study discontinuation, significant non-serious AEs, and SAEs will be identified. Individual subject listings will be provided, as necessary.

[redacted]

No inferential testing will be done for safety analysis.

[redacted]

6.10 Sample Size Justification

No formal sample size calculation is provided given the descriptive and pilot nature of the study.

7 ADVERSE EVENTS AND DEVICE DEFICIENCIES

Terms and Definitions

Adverse Event (AE)	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 (test product). *Note: For subjects, this definition includes events related to the test product, the control product, or the procedures involved. For users or other*

	persons, this definition is restricted to events related to the test product.
Adverse Device Effect (ADE)	AE related to the use of an investigational medical device (test *product*) or control *product*. *Note: This definition includes AEs resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation; any malfunction; and use error or intentional misuse of the test product or control product.*
Anticipated Serious Adverse Device Effect	Serious ADE which by its nature, incidence, severity or outcome has been identified in the risk management file.
Device Deficiency	Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. *Note: This definition includes malfunctions, use errors, and inadequate labeling.*
Malfunction	Failure of a medical device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling of the device. The intended performance of the device refers to the intended use for which the device is labeled or marketed.
Non-serious Adverse Event	AE that does not meet the criteria for an SAE.
Serious Adverse Event (SAE)	AE that led to any of the following: • Death. • A serious deterioration in the health of the subject that either resulted in: a) a life-threatening illness or injury. *Note: Life-threatening means that the individual was at immediate risk of death from the event as it occurred, ie, it does not include an event which hypothetically might have caused death had it occurred in a more severe form.* b) any potentially sight-threatening event or permanent impairment to a body structure or a body function. c) in-patient hospitalization or prolonged hospitalization. *Note: Planned hospitalization for a pre-existing condition, without serious deterioration in health, is not considered an SAE. In general, hospitalization signifies that the individual remained at the hospital or emergency ward for*

	observation and/or treatment (usually involving an overnight stay) that would not have been appropriate in the physician's office or an out-patient setting. Complications that occur during hospitalization are adverse events. If a complication prolongs hospitalization or fulfills any other serious criteria, the event is serious. When in doubt as to whether "hospitalization" occurred, the event should be considered serious. d) a medical or surgical intervention to prevent a) or b). e) any indirect harm as a consequence of incorrect diagnostic test results when used within manufacturer's instructions for use. • Fetal distress, fetal death, or a congenital abnormality or birth defect. *Refer to Section 7.1 for additional SAEs.*
Serious Adverse Device Effect (SADE)	ADE that has resulted in any of the consequences characteristic of an SAE.
Significant Non-Serious Adverse Event	A significant non-serious AE is a symptomatic, device-related, non-sight threatening AE that warrants discontinuation of any contact lens wear for greater than or equal to 2 weeks. *Refer to Section 7.1 for additional Significant Non-Serious AEs.*
Unanticipated Serious Adverse Device Effect	Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the risk management file.
Use Error	Act or omission of an act that results in a different medical device response than intended by manufacturer or expected by user. *Note: This definition includes slips, lapses, and mistakes. An unexpected physiological response of the subject does not in itself constitute a use error.*

7.1 General Information

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 (test *product*).

Figure 7–1 Categorization of All AEs

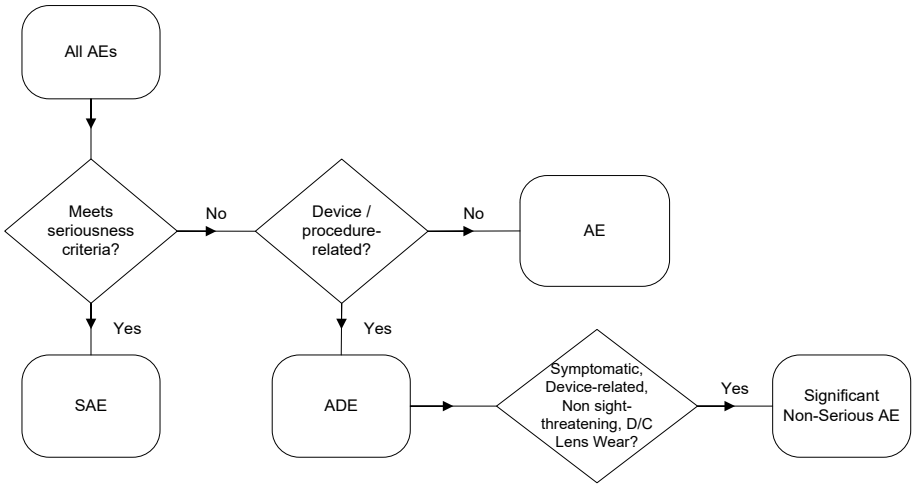
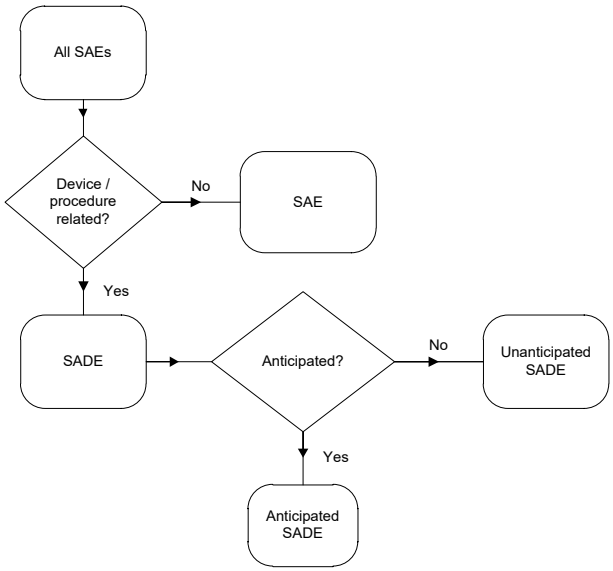


Figure 7-2 Categorization of All Serious Adverse Events



[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Device Deficiencies

A device deficiency is inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. [redacted]

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

7.2 Monitoring for Adverse Events

At each visit, after the subject has had the opportunity to spontaneously mention any problems, the Investigator should inquire about AEs by asking the standard questions:

- "Have you had any health problems since your last study visit?"
- "Have there been any changes in the medicines you take since your last study visit?"

Additionally, changes in *any protocol-specific parameters and/or questionnaires* evaluated during the study are to be reviewed by the Investigator. Any untoward (unfavorable and unintended) change in *a protocol-specific parameter or questionnaire response* that is clinically relevant, in the opinion of the Investigator, is to be reported as an AE. These clinically relevant changes will be reported regardless of causality.

7.3 Procedures for Recording and Reporting

AEs are collected from the time of informed consent. [redacted].

[redacted]

[redacted]

[redacted]

[redacted]

7.5 Follow-Up of Subjects with Adverse Events

The Investigator is responsible for adequate and safe medical care of subjects during the study and for ensuring that appropriate medical care and relevant follow-up procedures are maintained after the study.

[redacted]

[redacted]

[redacted]

[redacted]

8 CONFIDENTIALITY, BIAS, AND MASKING

8.1 Subject Confidentiality and Methods Used to Minimize Bias

The Investigator must ensure that the subject's anonymity is maintained throughout the course of the study. [redacted]

8.2 Unmasking of the Study Treatment

Masked information on the identity of the assigned medical device should not be disclosed during the study [redacted].

9 DATA HANDLING AND ADMINISTRATIVE REQUIREMENTS

9.1 Completion of Source Documents and Case Report Forms

The nature and location of all source documents will be identified to ensure that original data required to complete the eCRFs exist and are accessible for verification by the site monitor,

and all discrepancies shall be appropriately documented via the query resolution process. Study monitors are appointed by the Study Sponsor and are independent of study site staff. If electronic records are maintained, the method of verification must be determined in advance of starting the study.

[redacted]

[redacted]

10 ETHICS AND COMPLIANCE

This trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and the referenced directives, regulations, guidelines, and/or standards.

10.1 Compliance

The Investigator must ensure that all personnel involved in the conduct of the study are qualified to perform their assigned responsibilities through relevant education, training, and experience. The Investigator and all clinical study staff must conduct the clinical study in compliance with the protocol. Deviations from this protocol, regulatory requirements and/or GCP must be recorded and reported to the Sponsor prior to database lock. If needed, corrective and preventive action should be identified, implemented, and documented within the study records.

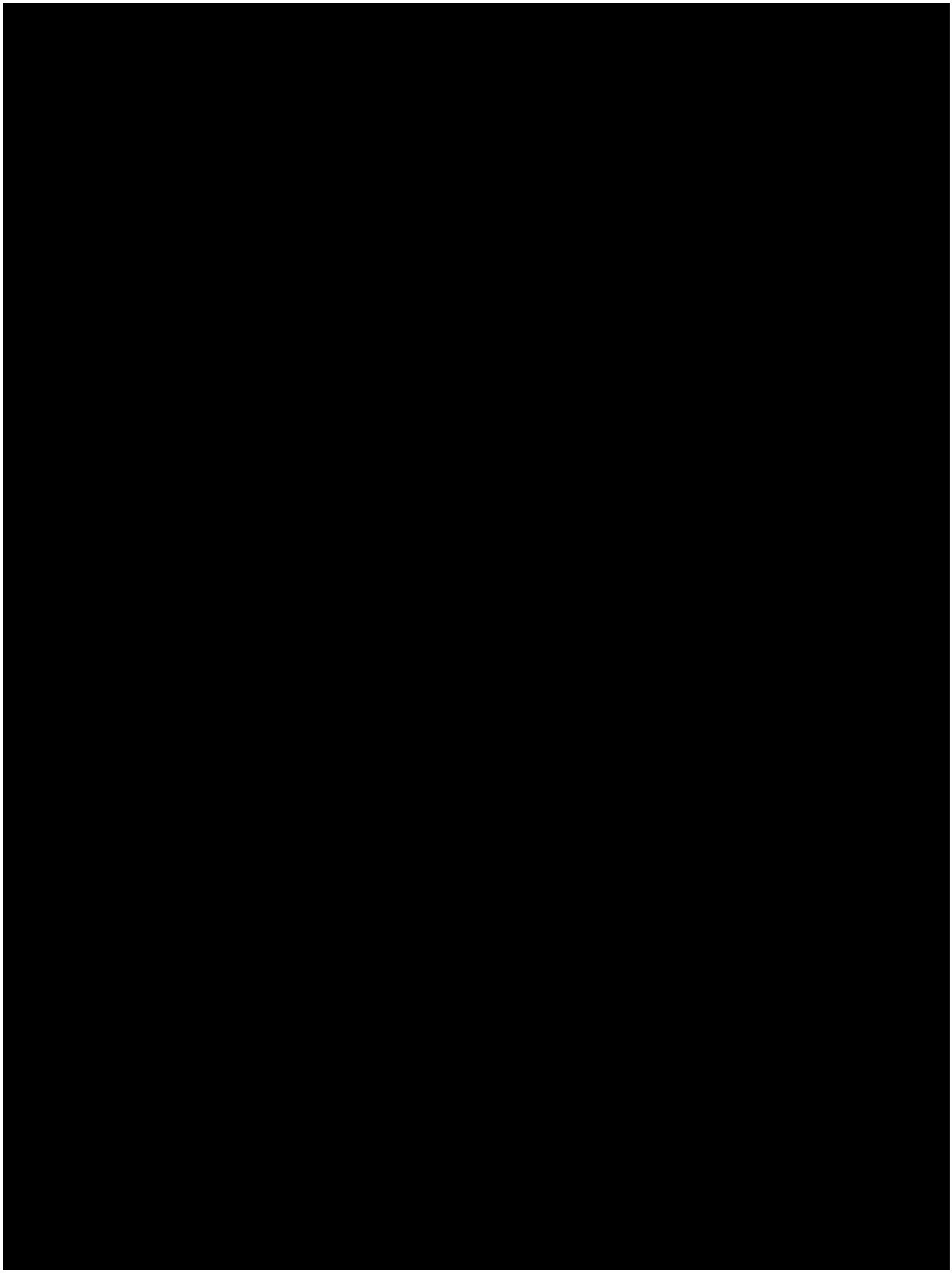
10.2 Institutional Review Board (IRB)

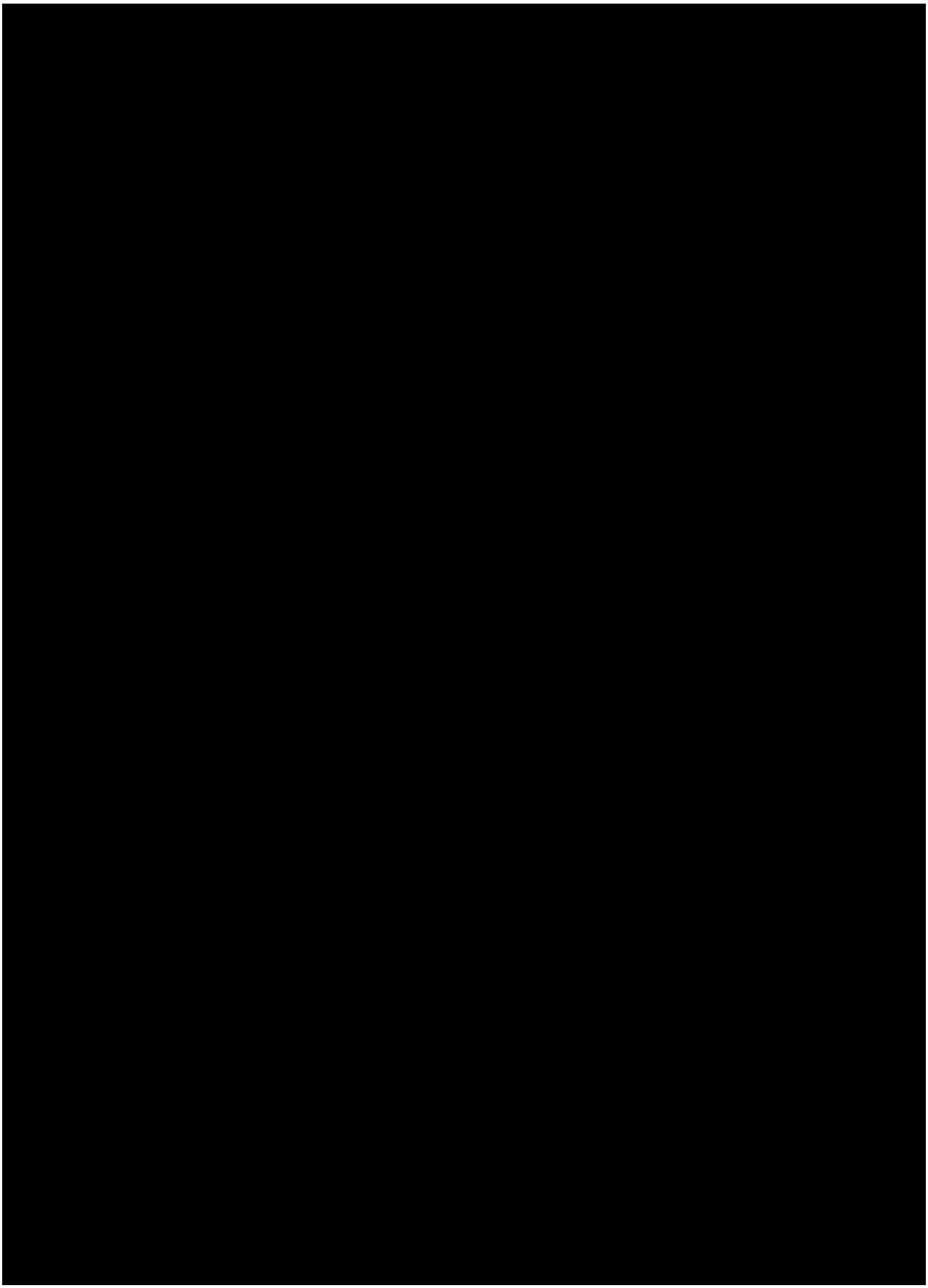
This trial requires IRB approval prior to initiation. This protocol, subject informed consent, and subsequent amendments will be reviewed and approved by an IRB.

Before clinical study initiation, this protocol, the ICF (and assent form, if applicable), any other written information given to subjects, and any advertisements planned for subject recruitment must be approved by an IRB. The Investigator must provide documentation of the IRB approval to the Study Sponsor. The approval must be dated and must identify the applicable protocol, amendments (if any), ICF, assent form (if any), all applicable recruiting materials, written information for subject, and subject compensation programs. The IRB must

be provided with a copy of the Investigator's Brochure and Package Insert, any periodic safety updates, and all other information as required by local regulation and/or the IRB. At the end of the study, the Investigator must notify the IRB about the study's completion. The IRB also must be notified if the study is terminated prematurely. Finally, the Investigator must report to the IRB on the progress of the study at intervals stipulated by the IRB.

Voluntary informed consent must be obtained from every subject (and/or legal representative, as applicable) prior to the initiation of any screening or other study-related procedures.





[redacted]

12 REFERENCES

12.1 References applicable for all clinical trials

- ISO 11980:2012 Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations
- ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice

12.1.1 US references applicable for clinical trials

- 21 CFR Part 11 - Electronic Records; Electronic Signatures
- 21 CFR Part 50 - Protection of Human Subjects
- 21 CFR Part 56 - Institutional Review Boards
- 21 CFR Part 812 - Investigational Device Exemptions
- 21 CFR Part 54 - Financial Disclosure by Clinical Investigators
- The California Bill of Rights

[redacted]

13 APPENDIX

13.1 Acuvue Oasys Package Insert

ACUVUE®

OASYS

BRAND CONTACT LENSES

ACUVUE OASYS® Brand Contact Lenses

ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM

ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA

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

INTRODUCTION

About This Booklet:

The information and instructions contained in this booklet apply only to the following brands:

- ACUVUE OASYS® Brand Contact Lenses,
- ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM , and
- ACUVUE OASYS® Brand Contact Lenses for PRESBYOPIA

For your eye health, it is important that your contact lenses be worn only as prescribed by your Eye Care Professional. Your Eye Care Professional should be kept fully aware of your medical history and will develop a total program of care based on your specific needs. He or she will review with you all instructions for lens handling and care, including how to safely and easily open the packaging. You will also be taught how to properly apply and remove lenses. This booklet will reinforce those instructions.

If you have any questions, always ask your Eye Care Professional.

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.

Special sections are included in the back of this booklet to record your specific prescribed wearing information as well as to record the contact information for your Eye Care Professional.

About Your Lenses and Contact Lens Wear:

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

These lenses are intended for the correction of nearsightedness (myopia) and farsightedness (hyperopia). They are also available for people who may have other conditions such as astigmatism or presbyopia.

SYMBOLS KEY

	Consult Instructions for Use
	Manufactured by or in
	Date of Manufacture
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CYL	Cylinder
AXIS	Axis
MAX ADD	Near ADD
LOW	"Low" near ADD
MID	"Medium" near ADD
HGH	"High" near ADD
	Quality System Certification Symbol
	UV-Blocking
	Fee Paid for Waste Management
	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)

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 conjunctiva
Cornea	Clear front part of the eye
Corneal Ulcer	A sore or lesion on the cornea
Inflammation	Swelling, redness, and pain
Presbyopia	A condition in which the natural lenses in the eyes lose some of their elasticity. This occurs normally with aging as the lenses lose some of their ability to change focus for different distances (loss of reading vision).

WEARING RESTRICTIONS & INDICATIONS

ACUVUE OASYS® Brand Contact Lenses are indicated for the correction of nearsightedness (myopia) and farsightedness (hyperopia) in people with non-diseased eyes who have 1.00D or less of astigmatism.

ACUVUE OASYS® Brand Contact Lenses for ASTIGMATISM are indicated for the correction of vision in people with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have 3.50D or less of astigmatism.

ACUVUE OASYS® Brand Contact Lenses for PRESBYOBIA are indicated for the correction of distance and near vision in people with non-diseased eyes who may have 0.75D or less of astigmatism.

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

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 Eye Care Professional for more information.

Your Eye Care Professional will determine your wearing schedule (how long you should wear your lenses each day) and your replacement schedule (when you should discard your lenses and use new ones). When prescribed for frequent/planned replacement wear, you may clean and disinfect the lenses using a chemical disinfection system only.

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

Your contact lenses may be prescribed in certain eye conditions and diseases as a bandaged lens for the cornea to relieve discomfort and act as a protective bandage. Your Eye Care Professional will tell you if you have such a condition and may prescribe additional medications or replacement schedules for your individual condition. You should never self-treat any condition with a contact lens or eye medications without first being seen by your Eye Care Professional.

WHEN LENSES SHOULD NOT BE WORN (CONTRAINDICATIONS)

When wearing contact lenses for vision correction, **DO NOT USE** these lenses when you have any of the following conditions:

- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable
- Severe dry eye
- Reduced corneal sensitivity
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions on the surface of the eye or surrounding tissues that may be induced or made worse by wearing contact lenses or use of contact lens solutions
- Irritation of the eye caused by allergic reactions to ingredients in contact lens solutions (i.e., rewetting drops). These solutions may contain chemicals or preservatives (such as mercury, Thimerosal, etc.) to which some people may develop an allergic response
- Any active eye infection
- If eyes become red or irritated

For THERAPUTIC USE, your Eye Care Professional may prescribe your contact lenses to aid in the healing process of certain ocular conditions that may include those listed above.

WARNINGS

What You Should Know About Contact Lens Wear:

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. IF YOU EXPERIENCE:

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

YOU SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PROFESSIONAL.

- When prescribed by your Eye Care Professional for daily wear (i.e., your Eye Care Professional instructs you to remove your lenses at the end of each day), you should not wear your lenses while sleeping. Clinical studies have shown that the risk of serious eye problems is increased when lenses are worn overnight.[1]
- Studies have shown that contact lens wearers who smoke have a higher rate of eye problems than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye.
- Proper use and care of your contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- The overall risk of serious eye problems may be reduced by carefully following directions for lens care, including cleaning the lens case.

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

Specific Instructions for Use and Warnings:

- **Water Activity**

  Instruction for Use

  Do not expose your contact lenses to water while you are wearing them.

  WARNING:
  Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If your lenses have been submersed in water when participating in water sports or swimming in pools, hot tubs, lakes, or oceans, you should discard them and replace them with a new pair. Ask your Eye Care Professional for recommendations about wearing your lenses during any activity involving water.

- **Soaking and Storing Your Lenses**

  Instruction for Use

  Use only fresh multi-purpose (contact lens disinfecting) solution each time you soak (store) your lenses.

  WARNING:
  Do not reuse or "top off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss, or blindness.

  "Topping-Off" is the addition of fresh solution to solution that has been sitting your case.

- **Discard Date on Multipurpose Solution Bottle**

  Instruction for Use

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

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

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

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

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

- **Rub and Rinse Time**

  Instruction for Use

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

WARNING:

- Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss, or blindness.

- Lens Case Care

  Instruction for Use

  - Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
  - Replace your lens case according to the directions given you by your eye care professional or the labeling that came with your case.
  - Contact lens cases can be a source of bacterial growth.

  WARNING:
  Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss, or blindness.

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 Eye Care Professional (see **"Lens Handling & Insertion" and "Lens Wearing" sections**).

General Precautions:

- If you wear your contact lenses to correct presbyopia using monovision you **may not** be able to get the best corrected visual acuity for either far or near vision. Visual needs are different for different people, so your Eye Care Professional should work with you when selecting the most appropriate type of lens for you.
- Always contact your Eye Care Professional 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 Eye Care Professional if you experience any problems with your lenses while taking such medications. Depending on your symptoms, your Eye Care Professional may recommend rewetting drops that are available for use with soft contact lenses or may recommend that you stop wearing contact lenses while you are using these 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 Eye Care Professional 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.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.

ADVERSE REACTIONS
POSSIBLE PROBLEMS WITH LENS WEAR AND WHAT TO DO)

Possible Problems

Be aware that problems can occur while wearing contact lenses and may or may not be associated with the following symptoms:

- burning, stinging and/or itchy eyes
- reduced lens comfort
- feeling of something in your eye (foreign body, scratched area)
- swelling or inflammation in or around the eyes
- eye redness
- eyelid problems
- watery eyes
- unusual eye secretions
- poor vision
- blurred vision
- rainbows or halos around objects
- sensitivity to light (photophobia)
- dry eyes

When any of the above symptoms occur, a serious eye condition may be present. You should **immediately be seen by your Eye Care Professional**, so that the problem can be identified and treated, if necessary, in order to avoid serious eye damage.

Recognizing Problems and What To Do

You should conduct a simple 3-part self-examination at least once a day. Ask yourself:

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

If you notice any problems, you should IMMEDIATELY REMOVE YOUR LENS. If the problem or discomfort stops, discard the lens and place a new fresh lens on the eye.

If after inserting the new lens, the problem continues, IMMEDIATELY REMOVE THE LENS AND CONTACT YOUR EYE CARE PROFESSIONAL.

Do NOT use a new lens as self-treatment for the problem.

During therapeutic use, an adverse effect may be due to the original disease or injury 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. To avoid serious eye damage, you should contact your Eye care Professional IMMEDIATELY if there is an increase in symptoms while wearing the lens.

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 Eye Care Professional. If you will not or cannot always follow the recommended care procedures, you should not attempt to wear contact lenses.

When you first get your lenses, be sure that you are able to put the lenses on and remove them (or have someone else available who can remove the lenses for you) before leaving your Eye Care Professional's office.

Step 1: Getting Started

It is essential that you learn and use good hygiene in the care and handling of your new 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 oily 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. It is best to put on your lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.

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

Step 2: Opening the Packaging

Multipack

Each multipack contains individually packaged lenses. Each lens comes in its own lens package designed specifically to keep it sterile. You may choose to keep your lenses inside the multipack for storage until you are ready to use them.

Lens Package

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

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

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 unless specifically indicated for that use.

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 moist, clean, and free of any nicks or tears. If the lens appears damaged, DO NOT use it. Use the next lens in the multipack.

  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 into your eye:

1. BE SURE THE LENS IS NOT INSIDE-OUT by following either 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.
   - Another method is to 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 Eye Care Professional 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, check for the following:

- The lens is not centered on the eye (see *"Step 5: Centering the Lens,"* next in this booklet).
- If the lens is centered, remove the lens (see "Removing Your Lenses") and check for the following:
  - Cosmetics or oils on the lens. Dispose of the lens and insert a new fresh lens.
  - The lens is on the wrong eye.
  - The lens is inside out (it would also not be as comfortable as normal). See *"Step 3: Placing the Lens on the Eye."*

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

Note: If a lens is noticeably uncomfortable upon insertion or becomes less comfortable than when it was first inserted, remove the lens immediately and contact your Eye Care Professional. If your examination of your eyes and the lenses shows any other problems, IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYE CARE PROFESSIONAL.

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.
- **Avoid** all harmful or irritating vapors and fumes while wearing lenses.

Water Activity

- Do not expose your contact lenses to water while you are wearing them.

Lubricating/Rewetting Solutions

- Your Eye Care Professional 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.
- **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.

Sticking (Non-Moving) Lens

- For your eye health, it is important that the lens moves freely on your eye.
- If the lens sticks (stops moving) on your eye, apply a few drops of the recommended rewetting solution. Wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, you should immediately consult your Eye Care Professional.

Sharing Lenses

- **Never** allow anyone else to wear your lenses. They have been prescribed to fit your eyes and to correct your vision to the degree necessary. Sharing lenses greatly increases the chance of eye infections.

Adhering to the Prescribed Wearing & Replacement Schedules

- **Never** wear your lenses beyond the amount of time recommended by your Eye Care Professional.
- **Always throw away** worn lenses as prescribed by your Eye Care Professional.

REMOVING YOUR LENSES

CAUTION: Always be sure the lens is on the cornea (in the center of your eye) b : 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.
2. There are two recommended methods of lens removal: the Pinch Method, and the Forefinger and Thumb Method. You should follow the method that is recommended by your Eye Care Professional.

   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.

   Forefinger and Thumb Method:
   Step 1. Place your hand or a towel under your eye to catch the lens.
   Step 2. Place your forefinger on the center of the upper lid and your thumb on the center of the lower lid.
   Step 3. Press in and force a blink. The lens should fall onto your hand or the towel.

   Note: The lens may come out, but remain on the eyelid, finger or thumb.
3. Remove the other lens by following the same procedure.
4. Follow the instructions in the next section, *"Caring for Your Lenses"*.

Note: If these methods of removing your lens are difficult for you, ask your Eye Care Professional for an alternate method.

CARING FOR YOUR LENSES

For Lenses Prescribed for Disposable Wear:

Remember, there is no cleaning or disinfection needed with your contact lenses when they are prescribed for disposable wear. Always dispose of lenses when they are removed and have replacement lenses or glasses available.

For Lenses Prescribed for Frequent Replacement:

When you first get your lenses, you will be given a recommended cleaning and disinfection routine and instructions and warnings for lens care, handling, cleaning, disinfection, and storage. Your Eye Care Professional should teach you about appropriate and adequate procedures and products for

your use.

When you remove your lenses between replacement periods, the lenses must be cleaned and disinfected before you put them back on your eyes, or you should throw them away and replace them with fresh lenses.

For continued safe and comfortable wearing of your lenses, it is important that you first clean and rinse, then disinfect [and neutralize (for hydrogen peroxide systems)] your lenses after each removal, using the lens care products and procedures recommended by your Eye Care Professional. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits that may have built up on your lenses during wearing. The ideal time to clean your lenses is immediately after removing them. Disinfecting is necessary to destroy harmful germs.

You should always use the recommended lens care routine. Failure to follow the recommended procedures may result in development of serious eye problems, as discussed in the "Warnings" section.

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.
- Make sure you have the following supplies available:
  - Fresh cleaning and disinfection solutions, or a multipurpose solution as recommended by your Eye Care Professional

    Never use solutions recommended for conventional hard contact lenses only.
  - Clean Lens Case

    When using hydrogen peroxide lens care systems, use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution.

Step 1: Cleaning & Disinfecting (Chemical – Not Heat)

1. Always clean and disinfect the same lens first to avoid mix-ups.
2. Follow the instructions provided in the cleaning & disinfection product labeling or as recommended by your Eye Care Professional.

   DO NOT heat the disinfection solution and lenses.

   Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution that may be irritating to the eyes. A thorough rinse in fresh sterile saline (or another recommended solution) prior to placement on the eye should reduce the potential for irritation.
3. If not using a multipurpose solution, after cleaning, rinse the lens thoroughly with a recommended rinsing solution to remove the cleaning solution, mucus, and film from the lens surface.

4. Rub and rinse your lenses according to the recommended lens rubbing and rinsing times in the labeling of your multipurpose solution to adequately disinfect your lenses.

   WARNING:

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

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

5. Put the lens into the correct chamber of the lens storage case.

   NOTE: When using hydrogen peroxide lens care systems, **use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution.** Failure to use the specialized case will result in severe stinging, burning, and injury to the eye. Follow the recommendations on the hydrogen peroxide system labeling exclusively. Following disinfection with a peroxide system, the lenses should be rinsed with sterile saline.

6. Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.

Step 3: Storage

- To store your lenses, first disinfect them, and then leave them in the closed/unopened case until you are ready to wear them.

  ALWAYS keep your lenses completely covered by a recommended disinfecting solution when the lenses are not being worn. Extended periods of drying will make it harder for the lens to become wet again. If a lens does become dried out, discard it and replace with a fresh new lens.

- If you will not be wearing your lenses immediately following disinfection, you should ask your Eye Care Professional for information about storing your lenses.
- Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
- Replace your lens case according to the directions given you by your eye care professional or the labeling that came with your case.
- Contact lens cases can be a source of bacterial growth.

WARNING: Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss, or blindness.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM RIGHT AWAY.

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (MONOVISION & MULTIFOCAL)

About Presbyopia and Vision Correction

- Presbyopia is a condition in which the natural lenses in the eyes lose some of their elasticity. This occurs normally with aging as the lenses lose some of their ability to change focus for different distances (loss of reading vision).
- Monovision is a method of correction for presbyopia using contact lenses in which one eye is corrected for distance vision and the other is corrected for near vision.
- Multifocal lenses correct presbyopia by providing distance and near vision correction powers within the same lens.

Getting Used to Monovision Correction (Adaptation)

- Be aware that, as with any type of lens correction, there are advantages and compromises to presbyopic contact lens correction. The benefit of clear near vision when looking straight-ahead and upward that you get with your contact lenses for monovision and multifocal correction may be accompanied by a vision compromise that may reduce the sharpness of your and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to this. Symptoms, such as mild blurred vision and variable vision, may last for a brief period or for several weeks as you are getting used to the lenses. The longer these symptoms last, the poorer your chances for successful adaptation may be.
- You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations that are not visually demanding. For example, it might be better to be a passenger rather than a driver of a car during the first days of lens wear. Also, it is recommended that you only drive with monovision or multifocal correction if you pass your state driver's license requirements with this correction.
- It is important that you follow your Eye Care Professional's suggestions for getting used to presbyopic contact lens correction. You should discuss any concerns that you may have during and after the adaptation period.

Additional Correction Needs

- Some patients with monovision correction will need to wear their glasses over their contact lenses to provide the clearest vision for critical tasks. You should discuss this with your Eye Care Professional.
- Some patients will never be fully comfortable functioning under low levels of lighting, such as driving at night. If this happens, you may want to discuss with your Eye Care Professional

having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required from both eyes together.

- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near vision is required from both eyes together.

The decision to be fit with monovision or multifocal correction is most appropriately left to your Eye Care Professional, in conjunction with you, after carefully considering and discussing your needs.

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In Canada: Johnson & Johnson Vision Care, division of Johnson & Johnson
In USA: Johnson & Johnson Vision Care, Inc.
Revision date 03/15
Revision number: AO-03-15-03

13.2 Biofinity® (comfilcon A) Package Insert

BIOFINITY® (comfilcon A)
Soft (Hydrophilic) Contact Lenses
For Planned Replacement

IMPORTANT: Please read carefully and keep this information for future use. This package insert is intended for the Eye Care Practitioner but, should be made available to patients upon request. The Eye Care Practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

SYMBOLS KEY

The following symbols may appear on the label or carton.

SYMBOL	DEFINITION	Reference
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner	81 FR 38911
	Caution / See Instructions for Wearers	BS EN ISO 15223-1 Table 1, Symbol 5.4.4
	Use by Date (expiration date)	BS EN ISO 15223-1 Table 1, Symbol 5.1.4
LOT	Batch Code	BS EN ISO 15223-1 Table 1, Symbol 5.1.5
STERILE	Sterile using Steam Heat	BS EN ISO 15223-1 Table 1, Symbol 5.2.5
	Manufacturer	BS EN ISO 15223-1 Table 1, Symbol 5.1.1
EC REP	Authorized representative in the European Community	BS EN ISO 15223-1 Table 1, Symbol 5.1.2
	Do not use if package is damaged	BS EN ISO 15223-1 Table 1, Symbol 5.2.8
	Consult Instructions for use	BS EN ISO 15223-1 Table 1, Symbol 5.4.3
	Date of manufacture	BS EN ISO 15223-1 Table 1, Symbol 5.1.3

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

DESCRIPTION

BIOFINITY (comfilcon A) contact lenses are available as spheric, aspheric, toric, multifocal, and toric multifocal lens designs.

The lenses are made from a material containing 48% water and 52% comfilcon A, a silicone-containing hydrogel. The lenses have a tint (phthalocyanine blue) which is added to make the lens more visible for handling.

BIOFINITY and BIOFINITY XR SPHERE (comfilcon A) contact lenses parameters:

- Diameter: 13.5 mm to 15.0 mm
- Base Curve: 8.0 mm to 9.5 mm
- Center Thickness: 0.065 mm to 0.60 mm (varies with power)
- Powers: -20.00 D to +20.0 D

BIOFINITY ENERGYS™ ASPHERE (comfilcon A) contact lenses parameters:

- Diameter: 13.5 mm to 15.0 mm
- Base Curve: 8.0 mm to 9.5 mm
- Center Thickness: 0.065 mm to 0.60 mm (varies with power)
- Powers: -20.00 D to +20.0 D

BIOFINITY TORIC (comfilcon A) and **BIOFINITY XR TORIC** (comfilcon A) contact lenses parameters:

- Diameter: 13.5 mm to 15.0 mm
- Base Curve: 8.0 mm to 9.5 mm
- Center Thickness: 0.08 mm to 0.60 mm (varies with power)
- Powers: -20.00 D to +20.0 D
- Cylinder: -0.25 D to -5.75 D
- Axis: 0° to 180°

BIOFINITY MULTIFOCAL (comfilcon A) and **BIOFINITY XR MULTIFOCAL** (comfilcon A) contact lenses parameters:

- Diameter: 13.5 mm to 15.0 mm
- Base Curve: 8.0 mm to 9.5 mm
- Center Thickness: 0.08 mm to 0.60 mm (varies with power)
- Powers: -20.00 D to +20.0 D
- Addition Powers: +0.50 D to +4.00 D

BIOFINITY TORIC MULTIFOCAL (comfilcon A) contact lenses parameters:

- Diameter: 13.5 mm to 15.00 mm
- Base Curve: 8.0 mm to 9.5 mm mm
- Center Thickness: 0.05 mm to 0.60 mm (varies with power)
- Powers: -20.00 D to +20.00 D
- Cylinder: -0.25 D to -5.75 D
- Axis: 0° to 180° in 5° increments
- Addition Powers: +0.25 D to +4.00 D

The physical/optical properties of the lens are:

- Refractive Index: 1.40
- Light Transmittance: >97%
- Surface Character Hydrophilic
- Water Content 48%
- Specific Gravity 1.04
- Oxygen Permeability: 128 x 10^{-11} (cm^2/sec)(ml O_2/ml x mmHg) 35°C (Coulometric method)

Call our Customer Service Department at (800) 341-2020 for current availability.

ACTIONS

When placed on the cornea in its hydrated state, the **BIOFINITY** (comfilcon A) Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS FOR USE

Spherical and Aspherical

BIOFINITY and **BIOFINITY XR** SPHERE (comfilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

BIOFINITY ENERGYS™ ASPHERE (comfilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Toric

BIOFINITY TORIC (comfilcon A) and **BIOFINITY XR** TORIC (comfilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -5.75 diopters.

Multifocal

BIOFINITY MULTIFOCAL (comfilcon A) and **BIOFINITY XR** MULTIFOCAL (comfilcon A) lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.50 to +4.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Toric Multifocal

BIOFINITY TORIC MULTIFOCAL (comfilcon A) lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatic corrections from -0.25 to -5.75 diopters.

The **BIOFINITY** (comfilcon A) Soft (Hydrophilic) Contact Lenses have been approved for extended wear for up to 6 nights /7 days of continuous wear. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Practitioner.

Eye Care Practitioners may prescribe the lens for frequent replacement wear, with cleaning, disinfecting and scheduled replacements (see WEARING SCHEDULE).

CONTRAINDICATIONS (REASONS NOT TO USE)

Do not use the **BIOFINITY** lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic.
- 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 any **BIOFINITY** lens.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS:

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

It is essential that the patient follows the directions of the Eye Care Practitioner and all labeling instructions for proper use of contact lenses and lens care products, including the lens case.

Patients should be advised of the following instructions for use and warnings pertaining to contact lens wear:

i. **Soaking and Storing the Lenses**

Instruction for Use:

Use only fresh multi-purpose (contact lens disinfecting) solution each time the patient soaks (stores) the lenses.

WARNING:

Do not reuse or "top off" old solution left in the lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness.

"Topping-Off" is the addition of fresh solution to solution that has been sitting in the case.

ii. **Rub and Rinse Time**

Instruction for Use:

- Rub and rinse the lenses according to the recommended lens rubbing and rinsing times in the labeling of the multi-purpose solution to adequately disinfect the lenses.

WARNING:

- Rub and rinse the lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

iii. **Lens Case Care**

Instruction for Use:

- Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to dry.
- Replace the lens case according to the directions given by the Eye Care Practitioner or the labeling that came with the case.
- Contact lens cases can be a source of bacterial growth.

WARNING:

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

iv. **Water Activity**

Instruction for Use:

- Do not expose the contact lenses to water while wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submersed in water when swimming in pools, lakes or oceans, discard them and replace them with a new pair. Ask the Eye Care Practitioner for recommendations about wearing the lenses during any activity involving water.

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

Instruction for Use:

- Discard any remaining solution after the recommended time period indicated on the bottle of multi-purpose solution used for disinfecting and soaking the contact lenses.
- The Discard date refers to the time to safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

WARNING:

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

- To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.
- To avoid contaminating the solution, DO NOT transfer to other bottles or containers.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE FOLLOWING IS EXPERIENCED:

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

PATIENTS SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PRACTITIONER.

- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

- Patients should be cautioned that proper use and care of the contact lenses and lens care products, including lens cases, are essential for the safe use of these products. It is essential that patients follow their Eye Care Practitioner's directions and all labeling instructions for proper use of lenses and lens care products. Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. Additionally, they should clean and rinse their lens case between uses as recommended by their Eye Care Practitioner. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision.**
- The result of a study[1] indicate the following:

a. The overall annual incidence of ulcerative keratitis in daily wear contact lens users is estimated to be about 4.1 per 10,000 persons and about 20.9 per 10,000 persons in extended wear contact lens users.

b. The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact lens users than for daily wear users. When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily basis are excluded from the comparison, the risk among extended wear users are 10 to 15 times greater than among daily wear users.

c. When daily users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is 9 times greater than among those who do not wear them overnight.

d. The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.

e. The risk of ulcerative keratitis among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.

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

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

PRECAUTIONS

Special Precautions for Eye Care Practitioners

- Due to the small numbers 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 Practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Practitioner.
- Patients who wear contact lenses to correct presbyopia 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.
- Aphakic patients should not be fitted with any **BIOFINITY** contact lenses until the determination is made that the eye has healed completely.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb the dye and become discolored. Whenever fluorescein is used in the eyes, the eyes should be

flushed with a sterile saline solution that is recommended for in-eye use.
- Before leaving the Eye Care Practitioner's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her. Eye Care Practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

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

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Never use solutions recommended for conventional hard contact lenses only.
- Always follow the directions in the package inserts for the use of contact lens solutions.
- Always use a chemical lens care system. Use of heat care system can damage the comfilcon A contact lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to **immediately** consult his or her Eye Care Practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as lens damage may occur.
- Always handle lenses gently and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, and wearing instructions in the Patient Instructions for **BIOFINITY** contact lenses and those prescribed by the Eye Care Practitioner.
- Never wear lenses beyond the period recommended by the Eye Care Practitioner.
- Always discard disposable lenses and lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the Eye Care Practitioner.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Ask the Eye Care Practitioner about wearing the lenses during sporting activities.
- Inform the doctor (Health Care Practitioner) about being a contact lens wearer.
- Always contact the Eye Care Practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- 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.

ADVERSE REACTIONS

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

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

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

- **Immediately remove the lenses.**
- If the discomfort or the problem stops, then look closely at the lens. If the lens is in some way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the Eye Care Practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect both lenses; then reinsert them. After reinsertion, if the problem continues the patient should **immediately remove the lenses and consult the Eye Care Practitioner.**

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

FITTING

Conventional methods of fitting contact lenses apply to all **BIOFINITY** contact lenses. For a detailed description of the fitting techniques, refer to the **BIOFINITY** Professional Fitting and Information Guide, copies of which are available from:

CooperVision, Inc.
711 North Road
Scottsville, New York 14546
1-800-341-2020
www.coopervision.com

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the Eye Care Practitioner. Patients tend to over-wear the lenses initially. The Eye Care Practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner are also extremely important.

CooperVision recommends that all **BIOFINITY** lenses be discarded and replaced with a new lens on a frequent replacement basis. The Eye Care Practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

DAILY WEAR: (less than 24 hours, while awake). The maximum suggested wearing time is:

DAY	Hours	Day	Hours
1	6	4	12
2	8	5	14
3	10	6	All waking hours

The Eye Care Practitioner should determine the wearing and replacement schedule, based upon the patient's history and their ocular examination, as well as the practitioner's experience and clinical judgment.

EXTENDED WEAR: BIOFINITY contact lenses may be prescribed for daily wear and extended wear for up to 6 nights/ 7 days of continuous day and night wear. Not all patients can achieve the maximum wear time. It is recommended that the contact lens wearer be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Practitioner.

Once removed, it is recommended that the lens remain out of the eye for a period of rest overnight or longer and discarded in accordance with the prescribed wearing schedule. The Eye Care Practitioner should determine the appropriate wearing time and provide specific instructions to the patient regarding lens care, insertion and removal.