a Novartis company

Title:

Clinical Performance of a Silicone Hydrogel for Daily Disposable Wear

Protocol Number:	CLE383-C003 / NCT03095027
Sponsor Name and Address:	Alcon Research, Ltd. 6201 South Freeway Fort Worth, Texas 76134-2099
Test Product(s):	Daily Disposable T2 Soft Contact Lenses (DD T2 Contact Lenses)
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, and all applicable regulatory requirements. Additionally, I will comply with all procedures for data recording and reporting, will permit monitoring, auditing, and inspection of my research center, and will retain all records until notified by the Sponsor.
Principal Investigator:	

Signature Date

[May be entered into the document or written/typed in later]

Name:
[Include professional position]
Address:

[redacted]

1 PROTOCOL SYNOPSIS

Trial Sponsor	Alcon Research, Ltd. 6201 South Freeway Fort Worth, Texas 76134-2099
Name of Test Product	Daily Disposable T2 Soft Contact Lenses (DD T2)
Name of Control Product	CooperVision® MyDay® (stenfilcon A) Daily Disposable Contact Lenses (MYDAY)
Title of Trial	Clinical Performance of a Silicone Hydrogel for Daily Disposable Wear
Protocol Number	CLE383-C003
Number of Sites Country	~3 US
Planned Duration of Exposure	~12 days total duration • Test Product: 6 days (±1 day) • Control Product: 6 days (±1 day)
Number of Subjects	Target to complete: 44 Planned to enroll: ~54
Study Population	Volunteer subjects aged 18 or over who are soft contact lens wearers (excluding previous or current MYDAY 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 8 hours per day. To qualify, subjects must require contact lenses in a power range from -1.50 D to -4.00 D.
Objective(s)	The primary objective of this study is to demonstrate noninferiority in visual acuity of DD T2 when compared to MYDAY. [redacted]
Endpoints	Primary Effectiveness • Visual acuity [redacted]

	[redacted] Safety • AEs • Device deficiencies • Biomicroscopy
Assessments	Effectiveness • VA (Snellen distance) • [redacted] • [redacted] • [redacted] • [redacted] • [redacted] • [redacted]

	Safety • AEs • Device deficiencies • Biomicroscopy	
Study Design	☒ Prospective ☐ Single group ☐ Parallel group ☒ Crossover ☐ Other	☐ Single-masked (trial subject) ☐ Single-masked (Investigator) ☒ Double-masked ☐ Open-label ☐ Other
	☐ Contralateral ☒ Bilateral ☐ Monocular lens wear	☒ Randomized
Test Product Details	Primary component/material	[redacted]
	Product Name	DD T2
	FID No.	122819
	Manufacturer	Alcon
	Other	The lenses will be available in -1.50 D to -4.00 D (0.25 D steps)
Control Product Details	Primary component/material	stenfilcon A
	Product Name	MYDAY
	Manufacturer	COOPERVISION
	Other	The lenses will be available in -1.50 D to -4.00 D (0.25 D steps)
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 soft contact lenses in both eyes for a minimum of 5 days per week and 8 hours per day during the past 3 months.	

	4. Manifest cylinder ≤ 0.75 D in each eye. 5. BCVA 20/25 or better in each eye.
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. 4. Ocular or intraocular surgery (excluding placement of punctal plugs) within the previous 12 months or planned during the study. 5. Biomicroscopy findings at screening that are moderate (Grade 3) or higher and/or corneal vascularization that is mild (Grade 2) or higher. 6. Current or history of pathologically dry eye in either eye that, in the opinion of the Investigator, would preclude contact lens wear. 7. Current or history of herpetic keratitis in either eye. 8. Eye injury in either eye within twelve weeks immediately prior to enrollment for this trial. 9. Any previous or current wear of MYDAY. 10. Habitually wearing monovision or multifocal lenses during the last 3 months. 11. Current or history of intolerance, hypersensitivity or allergy to any component of the study products. 12. 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. 13. Any use of topical ocular medications and artificial tear or rewetting drops that would require instillation during contact lens wear. 14. The Investigator, his/her staff, family members of the Investigator, family members of the Investigator's staff, or individuals living in the households of the

	aforementioned persons may not participate in the study. 15. Participation of the subject in a clinical trial within the previous 30 days or currently enrolled in any clinical trial.
Associated Materials	Lubrication/re-wetting drops will not be permitted.

Table 1-1 Schedule of Study Procedures and Assessments

Procedure/ Assessment	**Visit 1, Day 1: Baseline/Dispense Study Lens 1**	**Visit 2, Week 1: 6 Days (± 1 day) Follow-up Study Lens 1 / Dispense Study Lens 2**	**Visit 3, Week 2: 6 Days (± 1 Day) Follow-up Study Lens 2/ Exit**
Informed Consent	✓	-	-
Demographics	✓	-	-
Medical History	✓	-	-
Concomitant Medications	✓	✓	✓
Inclusion/Exclusion	✓	-	-
Habitual lens (brand, power)	✓	-	-
VA w/ habitual correction (OD, OS, Snellen distance)	✓	✓	✓
[redacted]			
Biomicroscopy	✓	✓	✓
Dispense study lenses	✓	✓	-
VA w/ study lenses (OD, OS, Snellen distance[1])	✓	✓	✓
[redacted]			

Procedure/ Assessment	Visit 1, Day 1: Baseline/Dispense Study Lens 1	Visit 2, Week 1: 6 Days (± 1 day) Follow-up Study Lens 1 / Dispense Study Lens 2	Visit 3, Week 2: 6 Days (± 1 Day) Follow-up Study Lens 2/ Exit
[redacted]			
AEs	✓	✓	✓
Device deficiencies	✓	✓	✓
Exit Form	(✓)	(✓)	(✓)

(✓) assessment performed as necessary, eg, decrease of VA by 2 lines or more with investigational product (IP)

[redacted]

[1] Primary effectiveness endpoint

1.1 Abbreviations

Abbreviation	Definition
ADE	Adverse device effect
AE	Adverse event
ASADE	Anticipated serious adverse device effect
BCVA	Best corrected visual acuity
CFR	Code of Federal Regulations
D	Diopter(s)
DD	Daily disposable
DD T2	Daily Disposable T2 Soft Contact Lenses
DEP	Deviations and Evaluability Plan
eCRF	Electronic case report form
EDC	Electronic data capture
FAS	Full analysis set
FDA	US Food and Drug Administration
FID	Formulation identification
GCP	Good Clinical Practice
[redacted]	[redacted]
IB	Investigator's brochure
ICF	Informed consent form
IEC	Independent ethics committee
IP	Investigational product
IRB	Institutional review board
ISO	International Organization for Standardization
LogMAR	Logarithm of the minimum angle of resolution
mm	Millimeter
MYDAY	COOPERVISION MYDAY (stenfilcon A) Daily Disposable Contact Lenses
N/A	Not applicable
OD	Right eye
OS	Left eye
OU	Both eyes
PP	Per protocol
pt	Point
Rx	Prescription
SAE	Serious adverse event
SADE	Serious adverse device effect
SiHy	Silicone hydrogel
US	United States
USADE	Unanticipated serious adverse device effect
VA	Visual acuity

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3 INTRODUCTION

3.1 Study Rationale and Purpose

Daily disposable (DD) lenses are worn for a full day, during waking hours, and then thrown away after usage. This modality of contact lens wear is generally preferable by certain subsets of the contact lens wearing population including, but not limited to, patients who have environmental allergies, patients who have excessive deposition of their non-DD lenses, younger patients where the eye care professional and/or the parent are unsure of the patient's ability to remove and clean a set of lenses on a daily basis, or patients who simply prefer not to use a daily cleaning and storage regimen.

New silicone hydrogel (SiHy) materials continue to be developed and each of these contains a unique set of properties. A new DD SiHy lens, known here as DD T2, has been developed that combines high oxygen transmissibility with a low modulus of elasticity.

In this clinical trial, the overall lens performance of the study lenses including VA [redacted] be assessed in a crossover design. The study lenses will be worn bilaterally and in a DD wear modality for approximately 1 week.

DD T2 is intended for the optical correction of refractive myopia in persons with non-diseased eyes.

The purpose of this study is to obtain on-eye performance data to inform contact lens product development. There are no immediate plans to submit the results of this study for publication; however, the results may be offered for publication if they are of scientific interest, or if the results relate to a product that is subsequently approved or cleared for marketing. The design of this study is justified based upon preclinical and clinical testing, as described within the Investigator's Brochure (IB).

3.2 Trial Objective

The primary objective of this study is to demonstrate noninferiority in VA of DD T2 when compared to MYDAY.

[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 DD T2 are features consistent with successful contact lens wear.

Based upon nonclinical testing and documented rationale for applicability of test results, DD T2 are assessed to be non-toxic and biocompatible for on-eye use.

MYDAY is for daily wear use under a DD wear modality; further details on any known potential risks and benefits can be found in the package insert. Refer to Appendix, Section 13.

DD T2 and MYDAY are not intended for use with a cleaning/disinfecting solution, and the biocompatibility with lens care solutions and any associated clinical effects are unknown.

A summary of the known potential risks and benefits associated with DD T2 can be found in the IB. Risks are minimized by compliance with the eligibility criteria and study procedures, and through close supervision by a licensed clinician during exposure to the study lenses. The potential harms associated with on-eye exposure to the new lens materials include toxicity response, blurred vision and ocular discomfort. In general, the risks with DD T2 are anticipated to be similar to other marketed DD soft contact lenses.

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. 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 includes approximately 54 subjects to be enrolled at approximately 3 sites, with approximately 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 (excluding previous or current MYDAY wearers) in both eyes. To qualify, subjects must require contact lenses in a power range from -1.50 D to -4.00 D.

Subjects must be screened according to the full list of inclusion/exclusion criteria in Section 1 of this protocol. Rescreening of subjects is not allowed in this study.

3.5 Outline of Study

This will be a multi-site, prospective, randomized, crossover, double-masked study comparing 2 contact lenses worn in a daily wear, daily disposable modality for approximately 6 days each. The expected duration of subject participation in the study is approximately 2 weeks, with 3 scheduled visits. The study is expected to be completed in approximately 1 month. The effectiveness and safety assessments along with their collection time points are presented in Table 1-1.

4 TREATMENTS ADMINISTERED

Subjects will be randomized in a 1:1 manner to receive treatment in a crossover sequence: Test product then Control product or Control product then Test product, respectively.

4.1 Identity of Study Treatments

DESCRIPTION OF TEST AND CONTROL PRODUCTS		
	TEST	CONTROL
Lens	DD T2	MYDAY
Material	[redacted]	stenfilcon A
Water Content	51%	54%
Base Curve (mm)	8.3	8.4
Diameter (mm)	14.2	14.2
Rx powers (D) to be available in this study	-1.50 to -4.00 (0.25 steps)	-1.50 to -4.00 (0.25 steps)
Packaging, Labeling, and Supply	• Blister foil pack • Foil label includes: - material name and identifier - base curve - diameter - manufacturing protocol number - packing solution - power - lot number - expiration date - content statement - investigational	• Blister foil pack • Commercial foil with Half Over-label - material name - base curve - diameter - packing solution - power - lot number - expiration date - content statement - investigational device statement - country of origin.

	device statement - sponsor information - country of origin. • Provided in boxes of 10 lenses per power per box, identified with the following: - a label stating the protocol number - material identifier - power - an investigational use only statement - tracking number. • Lenses should be stored at room temperature.	• Provided in boxes of 10 lenses per power per box, identified with the following: - a label stating the protocol number - material identifier - power - an investigational use only statement - tracking number. • Lenses should be stored at room temperature.
Usage	• Wear: o Daily Wear o Bilateral, Crossover • Replacement period: DD • Exposure: At least 8 hours per day, 5 days per week over the study duration, 6-day (±1 day) window per product • Lens Care: N/A	

4.2 Accountability Procedures

Upon receipt of the study lenses, the Investigator or delegate will conduct an inventory. Designated study staff will provide the study lenses to the subjects in accordance with their randomization schedule. Throughout the study, the Investigator or delegate must maintain records of study treatment dispensation and collection for each subject. This record must be made available to the study monitor for the purposes of verifying the accounting of clinical supplies. Any discrepancies and/or deficiencies between the observed disposition and the written account must be recorded along with an explanation.

It is the Investigator's responsibility to ensure that:

- All study products are accounted for and not used in any unauthorized manner
- All used foils and unused supplies are returned by each subject
- All unused products are available for return to the Study Sponsor, as directed
- Any study lenses associated with a device deficiency or with any product-related adverse event [ie, ADE or SADE] are returned to the Study Sponsor for investigation. Refer to Section 7.3 of this protocol for additional information on the reporting of device deficiencies and AEs and the return of study products associated with these events.

5 STUDY PROCEDURES AND ASSESSMENTS

5.1 Visits and Examinations

5.1.1 Visit 1 (Day 1) – Baseline/Dispense Study 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. Include herbal therapies, vitamins, and all over-the-counter as well as prescription medications.
3	[redacted]
4	Perform Snellen VA with habitual correction. • OD, OS, distance only, contact lenses* • Record habitual lens information (brand, power). **Record in Source Document only.*
5	[redacted]
6	[redacted]

7	Perform slit-lamp biomicroscopy (without contact lenses) to evaluate the following: • Limbal hyperemia • Bulbar hyperemia • Corneal staining • Conjunctival staining • Corneal vascularization • Corneal epithelial edema • Corneal stromal edema • Conjunctival compression/indention • Chemosis • Palpebral conjunctival observations • Corneal infiltrates • Other findings
8	[redacted]
9	Review inclusion/exclusion criteria to determine if the subject qualifies to be randomized into the study. If subject qualifies, request randomization.
10	Based upon the randomized treatment sequence assignment, have the subject insert the appropriate study lenses. • *Keep all lidding foils of lenses used during lens fit process for study lens accountability.* • *Follow procedures to maintain masking.*
11	[redacted]
12	Evaluate the study lenses by performing the following: • Snellen VA with study lenses (OD and OS, at distance)** • Over-refraction if necessary to determine the best contact lens-corrected VA and final study lens power(s) ***VA w/study lenses must be 20/40 OU or better for subject to leave the office*

13	[redacted]
14	[redacted]
15	Assess and record any AEs and device deficiencies reported or observed during the study visit. *Note: AEs and device deficiencies must be recorded for all enrolled subjects from the time of signature of informed consent including those that screen fail.*
16	Dispense study lenses and instruct the subject on lens wear.
17	Schedule Visit 2 to take place 6 days (± 1 day) after Visit 1.

5.1.2 Visit 2 (6 Days ± 1 Day) – Follow-up Study Lens 1 / Dispense Study Lens 2

1	Obtain information on any changes in medical health and/or the use of concomitant medications.
2	Record any device deficiencies or AEs that are observed or reported, including those associated with changes in concomitant medication dosing since the previous visit(s).
3	Review subject compliance with lens wear.
4	[redacted]
5	Evaluate the study lenses by performing the following: • Snellen VA with study lenses (OD and OS, at distance) *Note: Perform BCVA if there is a decrease of VA by 2 lines or more with IP*

6	[redacted]
7	[redacted]
8	Have subject remove study lenses.
9	Perform slit-lamp biomicroscopy (without contact lenses) to evaluate the following: • Limbal hyperemia • Bulbar hyperemia • Corneal staining • Conjunctival staining • Corneal vascularization • Corneal epithelial edema • Corneal stromal edema • Conjunctival compression/indention • Chemosis • Palpebral conjunctival observations • Corneal infiltrates • Other findings
10	Based upon the randomized treatment sequence assignment, have the subject insert the appropriate study lenses to be evaluated. • *Keep all lidding foils of lenses used during lens fit process for study lens accountability.* • *Follow procedures to maintain masking.*
11	[redacted]
12	Evaluate the study lenses by performing the following: • Snellen VA with study lenses (OD and OS, at distance)* • Over-refraction if necessary to determine the best contact lens-corrected VA and final study lens power(s) **VA w/study lenses must be 20/40 OU or better for subject to leave the office*

13	[redacted]
14	[redacted]
15	Schedule Visit 3 to take place 6 days ± 1 day after Visit 2.

5.1.3 Visit 3 (6 Days ± 1 Day) - Follow-up Study Lens 2 / Exit Visit

1	Obtain information on any changes in medical health and/or the use of concomitant medications.
2	Record any device deficiencies or AEs that are observed or reported, including those associated with changes in concomitant medication dosing since the previous visit(s).
3	Review subject compliance with lens wear and adjunct product usage.
4	[redacted]
5	Evaluate the study lenses by performing the following: • Snellen VA with study lenses (OD and OS, at distance) *Note: Perform BCVA if there is a decrease of VA by 2 lines or more with IP*
6	[redacted]
7	[redacted]
8	Have subject remove the study lenses.

9	Perform slit-lamp biomicroscopy (without contact lenses) to evaluate the following: • Limbal hyperemia • Bulbar hyperemia • Corneal staining • Conjunctival staining • Corneal vascularization • Corneal epithelial edema • Corneal stromal edema • Conjunctival compression/indention • Chemosis • Palpebral conjunctival observations • Corneal infiltrates • Other findings
10	Perform Snellen VA with habitual correction*. • OD, OS, distance only • Over-refraction (only needed if VA is reduced) **Record in source document only*
11	Exit the subject from the study.

5.2 Unscheduled Visits

If a subject visit occurs between any regularly scheduled visits then this visit must be documented as an Unscheduled Visit. 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 applicable)

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.

5.3 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 (ie, their subject numbers will not be re-assigned/re-used).

Should a subject exhibit any clinically relevant signs, symptoms, or other clinical observations that possibly could be associated with suspected sensitivity or intolerance to one of the study treatments, the Investigator must document those observations on an AE Form.

Any subject who exits early from the study must undergo all procedures outlined at Visit 3, as applicable.

The Investigator must document the reason for study or treatment discontinuation in the subject's case history source documents.

To ensure the safety of all subjects who discontinue early, Investigators must assess each subject and, if necessary, advise them of any therapies and/or medical procedures that may be needed to maintain their health.

5.4 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.

If the clinical study is prematurely terminated or suspended by the Study Sponsor:

- The Study Sponsor must:
    - Immediately notify the Investigator(s) and subsequently provide instructions for study termination.
    - Inform the Investigator and the regulatory authorities of the termination/suspension and the reason(s) for the termination/suspension, as applicable.
- The Investigator must:
    - Promptly notify the IRB of the termination or suspension and of the reasons.
    - Provide subjects with recommendations for post-study treatment options as needed.

The Investigator may terminate a site's participation in the study for reasonable cause.

6 ANALYSIS PLAN

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 will be determined prior to breaking the code for masked treatment (lens) sequence assignment and locking the database, based upon the Deviations and Evaluability Plan (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.

6.2.2 Full Analysis Set

The full analysis set (FAS) is the set of all randomized subjects who are exposed to any study lenses evaluated in this study.

6.2.3 Per Protocol Analysis Set

The per protocol (PP) analysis set is a subset of FAS and excludes all data which have met any of the critical deviation or evaluability criteria identified in the DEP.

6.3 Demographic and Baseline Characteristics

Demographic information (age, sex, ethnicity, race) will be summarized on the safety, full, and PP analysis sets. Baseline data pertaining to habitual lens (lens brand, power, [redacted]) will be summarized on the full and PP analysis sets.

6.4 Effectiveness Analyses

This study defines one primary effectiveness endpoint, [redacted] The FAS will serve as the primary set for all effectiveness analyses. [redacted]

[redacted]

6.4.1 Primary Effectiveness

The primary objective of this study is to demonstrate noninferiority in VA of DD T2 when compared to MYDAY.

The primary endpoint is VA (logMAR) at Dispense and Week 1, Follow-Up.

6.4.1.1 Statistical Hypotheses

The null and alternative hypotheses are formulated in terms of the predefined margin of 0.05 for noninferiority:

H_0: $\mu_{(DDT2)} - \mu_{(MYDAY)} \geq 0.05$

H_a: $\mu_{(DDT2)} - \mu_{(MYDAY)} < 0.05$

where $\mu_{(DDT2)}$ and $\mu_{(MYDAY)}$ denote the mean VA for DD T2 and MYDAY, respectively.

6.4.1.2 Analysis Methods

A mixed effect repeated measures model will be utilized to test these hypotheses. The model will include terms for lens, visit, lens by visit interaction, period, and sequence. Within-subject correlation due to eye and the crossover will also be accounted for in the model. Lens difference (DD T2 minus MYDAY) and the corresponding one-sided 95% upper confidence limit will be computed. Noninferiority in VA will be declared if upper confidence limit is less than 0.05.

6.4.2 Secondary Effectiveness

Not applicable.

6.4.2.1 Statistical Hypotheses

Not applicable.

6.4.2.2 Analysis Methods

Not applicable.

6.5 Subgroup Analyses

It is not expected that demographic or baseline characteristics will have an impact on the results in this study. No subgroup analyses are planned.

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.

6.8 Safety Analysis

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

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 nonserious AEs, and SAEs will be identified. Individual subject listings will be provided, as necessary.

Individual subject listings will be provided for AEs that occur after signing informed consent but prior to exposure to study lenses. This listing will include the following variables: lens sequence assigned, Investigator, subject, age, sex, eye (if ocular), in addition to relevant data describing the AE.

Each biomicroscopy parameter will be tabulated by its grade. For each biomicroscopy parameter, counts and percentages of eyes that experience an increase of ≥ 2 grades from baseline (Visit 1) to any subsequent visit within the specific crossover period will be presented. A supportive listing will be generated which will include all biomicroscopy data from all visits within the affected period for these eyes experiencing the increase, with the following variables: lens, Investigator, subject, age, sex, visit, eye, parameter, baseline value, and value at the visit.

Two listings (prior to exposure of study lenses and treatment-emergent) of device deficiencies, as recorded on the Device Deficiency Form, will be provided. Additionally, each device deficiency category will be tabulated. Each listing will include the following variables: lens, Investigator, subject, age, sex, in addition to relevant data describing the device deficiency and associated ADE, if any.

No inferential testing will be done for safety analysis.

6.9 Interim Analyses

There are no plans to conduct an interim analysis and no criteria by which the study would be terminated early based upon statistical determination.

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 article). *Note: For subjects, this definition includes events related to the test article, the control article, or the procedures involved. For users or other persons, this definition is restricted to events related to the test article.*
Adverse Device Effect (ADE)	AE related to the use of an investigational medical device (test article) or control article. *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 article or control article.*
Anticipated Serious Adverse Device Effect (ASADE)	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.
Nonserious 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 Nonserious Adverse Event	A significant nonserious 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 for additional Significant Nonserious AEs.*
Unanticipated Serious Adverse Device Effect (USADE)	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 article).

Figure 7–1 Categorization of All AEs

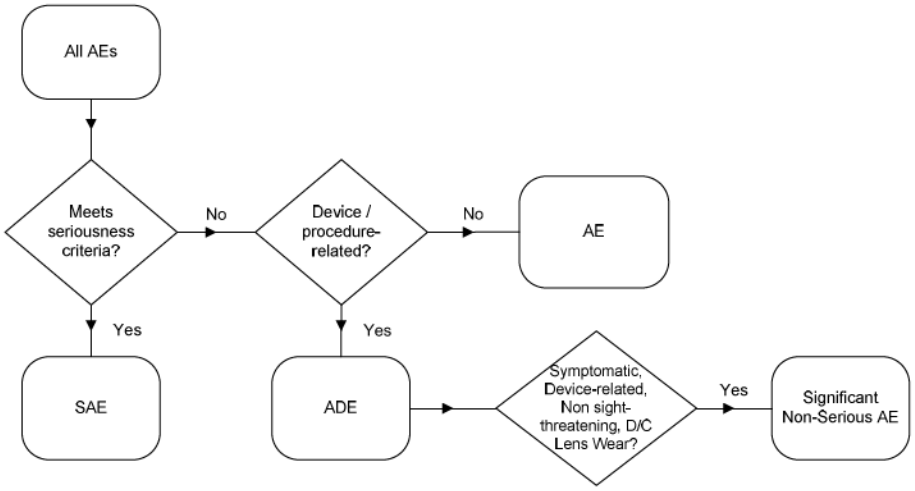
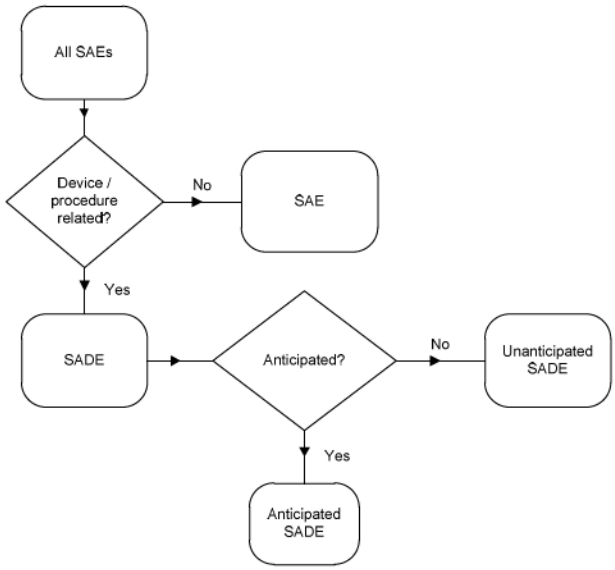


Figure 7-2 Categorization of All Serious Adverse Events



Serious Adverse Events

In addition to reporting all AEs (serious and nonserious) meeting the definitions, the Investigator must report any occurrence of the following as an SAE:

- An ocular infection including a presumed infectious ulcer with any of the following characteristics:
    - Central or paracentral location
    - Penetration of Bowman's membrane

- Infiltrates > 2 mm diameter
- Iritis
- Increase in intraocular pressure
- Culture positive for microorganisms
- Increasing size or severity at subsequent visits

- Any central or paracentral corneal event (such as neovascularization) that results in permanent opacification
- Hypopyon
- Hyphema
- Neovascularization within the central 6 mm of the cornea
- Permanent vision loss as defined by loss of 2 or more lines of BCVA from enrollment visit that fails to resolve
- Uveitis (anterior, intermediate, or posterior)
- Corneal abrasion affecting ≥ 50% of corneal surface area

Significant Nonserious Adverse Events

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. In addition, the Investigator must report any occurrence of the following as a Significant Nonserious AE:

- Peripheral non-progressive non-infectious ulcers
- All symptomatic corneal infiltrative events
- Corneal staining score greater than or equal to Grade 3 [Grading scale is based upon ISO 11980:2012 unless otherwise specified]
- Temporary vision loss as defined by loss of 2 or more lines of BCVA from enrollment visit that persists for 2 or more weeks
- Neovascularization score greater than or equal to Grade 2 [Grading scale is based upon ISO 11980:2012 unless otherwise specified]

The above events are based upon the categories provided in the ISO 11980 and the US FDA Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses and Contact Lens Care Products.

Device Deficiencies

A device deficiency is inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. A device deficiency may or may not be associated with patient harm (ie, ADE or SADE); however, not all ADEs or SADEs are due to a device deficiency. The Investigator should determine the applicable category listed in the Device Deficiency eCRF for the identified or suspect device deficiency and report any patient harm separately. Examples of device deficiencies include the following:

- Failure to meet product specifications (eg, incorrect lens power/diameter/base curve/color)
- Lens cloudy
- Lens surface/edge defect
- Torn lens during handling/in pack
- Packaging deficit (eg, mislabeled product)
- Suspect product contamination
- Lack of performance

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. Any pre-existing medical conditions or signs/symptoms present in a subject prior to the start of the study (ie, before informed consent is signed) are not considered AEs in the study and should be recorded in the Medical History section of the eCRF.

In addition, temporary lens awareness or visual changes during the fitting process are not considered AEs if the Investigator assesses that the symptom(s) can reasonably resolve within the anticipated adaptation period.

- ADEs or SAEs are documented on the *Serious Adverse Event and Adverse Device Effect* eCRF within 24 hours of the Investigator's or site's awareness.
- Device deficiencies are documented on the *Device Deficiency* eCRF within 24 hours of the Investigator's or site's awareness.
- A printed copy of the completed *Serious Adverse Event and Adverse Device Effect* and/or *Device Deficiency* eCRF must be included with product returns.
- Additional relevant information after initial reporting must be entered into the eCRF as soon as the data become available.
- Document any changes to concomitant medications on the appropriate eCRFs.
- Document all relevant information from Discharge Summary, Autopsy Report,
- Certificate of Death, etc, if applicable, in narrative section of the *Serious Adverse Event and Adverse Device Effect* eCRF.

Note: Should the EDC system become non-operational, the site must complete the appropriate paper *Serious Adverse Event and Adverse Device Effect* and/or *Device Deficiency* Form. The completed form is emailed to the Study Sponsor at ftw.medical_safety@alcon.com according to the timelines outlined above; however, the reported information must be entered into the EDC system once it becomes operational.

Any AEs and device deficiencies for non-study marketed devices/products will be considered and processed as spontaneous (following the post-market vigilance procedures) and should be communicated to the device's/product's manufacturer as per local requirements.

Study Sponsor representatives may be contacted for any protocol related question.

Further, depending upon the nature of the AE or device deficiency being reported, the Study Sponsor may request copies of applicable portions of the subject's medical records. The Investigator must also report all AEs and device deficiencies that could have led to a SADE according to the requirements of regulatory authorities or IRB/IEC.

Intensity and Causality Assessments

Where appropriate, the Investigator must assess the intensity (severity) of the AE based upon medical judgment with consideration of any subjective symptom(s), as defined below:

Intensity (Severity)

Mild	An AE is mild if the subject is aware of but can easily tolerate the sign or symptom.
Moderate	An AE is moderate if the sign or symptom results in discomfort significant enough to cause interference with the subject's usual activities.
Severe	An AE is severe if the sign or symptom is incapacitating and results in the subject's inability to work or engage in their usual activities.

For every AE in the study, the Investigator must assess the causality (Related or Not Related to the medical device or study procedure). An assessment of causality will also be performed by Study Sponsor utilizing the same definitions, as shown below:

Causality

Related	An AE classified as related may be either definitely related or possibly related where a direct cause and effect relationship with the medical device or study procedure has not been demonstrated, but there is a reasonable possibility that the AE was caused by the medical device or study procedure.
Not Related	An AE classified as not related may either be definitely unrelated or simply unlikely to be related (ie, there are other more likely causes for the AE).

The Study Sponsor will assess the AEs and may upgrade the Investigator's assessment of seriousness and/or causality. The Study Sponsor will notify the Investigator of any AEs that are upgraded from nonserious to serious or from unrelated to related.

7.4 Return product analysis

Alcon products associated with device deficiencies and/or product related AEs should be returned and must include the Complaint # which will be provided by Study Sponsor after the case is entered in the Study Sponsor's Global Product Complaint Management System. These products should be returned to the Sponsor at the end of the study, unless instructed otherwise by the Sponsor.

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.

The Investigator should provide the Study Sponsor with any new safety information (which includes new AEs and changes to previously reported AEs) that may affect the safety evaluation of the device. For AEs that are unresolved/ ongoing at time of subject exit from study, any additional information received at follow-up should be documented in the eCRFs up to study completion (ie, database lock).

Any additional data received up to 1 month after subject discontinuation or exit must be documented and available upon the Study Sponsor's request. All complaints received after this time period will be considered and processed as spontaneous and should be communicated to the medical device's manufacturer as per local requirements.

The Investigator should also report complaints on non-Alcon products directly to the manufacturer as per the manufacturer's instructions or local regulatory requirements.

7.6 Pregnancy in the Clinical Study

Women of childbearing potential or women who are pregnant at the time of study entry are not excluded from participation. Pregnancy should be included in the Medical History section of the eCRF when a pregnant woman enters the study or if a woman becomes pregnant during the study. Pregnancy is not reportable as an AE; however, complications may be reportable and will be decided on a case–by-case basis.

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. In particular, the Investigator must keep an enrollment log with

confidential identifying information that corresponds to the subject numbers and initials of each study participant. At the end of the clinical study, the Sponsor will collect a copy of the enrollment log without any identifying subject information. All documents submitted to the Sponsor will identify the subjects exclusively by number and demographic information. No other personally identifying information should be transmitted to the Sponsor.

This study is double-masked with subjects randomized to use both DD T2 and MYDAY (in a randomized sequence) for the duration of the 2-week treatment period. The Investigator, [redacted] and Sponsor personnel (other than site monitors, lead clinical site manager, person responsible for generating the randomization schedule, and unmasked clinical data managers) involved in reporting, obtaining, and/or reviewing the clinical evaluations will be masked to the identity of the contact lens being administered. This level of masking will be maintained throughout the conduct of the study. Unmasking will occur only after all planned study data have been validated, and the database locked. Masked study personnel must avoid seeking information that may compromise masking. Unmasked study personnel must not disseminate information that is potentially unmasking to any masked personnel. The **masked** and **unmasked** site personnel must coordinate all study activities as necessary to protect masking and minimize bias during the trial.

8.2 Unmasking of the Study Treatment

Masked information on the identity of the assigned medical device should not be disclosed during the study. If the treatment code needs to be broken in the interest of subject safety, the Investigator is encouraged to contact an appropriate Study Sponsor representative prior to unmasking the information if there is sufficient time. Dependent upon the individual circumstances (ie, medical emergency), the code may be broken prior to contact with the Study Sponsor. The Study Sponsor must be informed of all cases in which the code was broken and of the circumstances involved. Additionally, the Study Sponsor may be required to unmask the information in order to fulfill expedited regulatory reporting requirements.

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.

At a minimum, source documents should include the following information for each subject:

- Subject identification (name, sex, race/ethnicity)
- Documentation of subject eligibility
- Date of informed consent
- Dates of visits
- Documentation that protocol specific procedures were performed
- Results of study parameters, as required by the protocol
- IP accountability records
- Documentation of AEs and other safety parameters (if applicable)
- Records regarding medical histories and the use of concomitant therapies prior to and during the study
- Date of study completion and reason for early discontinuation, if applicable

It is required that the author of an entry in the source documents be identifiable. Direct access to source documentation (medical records) must be allowed for the purpose of verifying that the data recorded on the eCRF are consistent with the original source data.

Only designated individuals may complete the eCRFs. The eCRFs will be submitted at regular intervals following the clinical study visit schedule. It is expected that all data reported will have corresponding entries in the source documents. The Principal Investigator is responsible for reviewing and certifying that the eCRFs are accurate and complete. The only subject identifiers recorded on the eCRFs will be subject number, and subject demographic information.

9.2 Data Review and Clarifications

Upon completion of the eCRFs, a targeted review of the eCRF data to the subject's source data will be completed by the site monitor to ensure completeness and accuracy. Additional data clarifications and/or additions may be needed as a result of the data cleaning process. Data clarifications are documented and are part of each subject's eCRFs.

9.3 Regulatory Documentation and Records Retention

The Investigator is required to maintain up-to-date, complete regulatory documentation as indicated by the Sponsor and the Investigator's files will be reviewed as part of the ongoing

study monitoring. Financial disclosure is not subject to regulatory inspection and should be kept separately.

Additionally, the Investigator must keep study records and source documents until the Sponsor provides written approval for their destruction. If the Investigator retires, relocates, or for any other reason withdraws from responsibility of keeping the study records, the Sponsor must be notified and suitable arrangements made for retention of study records and source documents needed to comply with national and international regulations (generally 2 years after discontinuing clinical development or after the last marketing approval).

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 IB, 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. The Investigator must have a defined process for obtaining consent. Specifically, the Investigator, or delegate, must explain the clinical study to each potential subject and the subject must indicate voluntary consent by signing and dating the approved informed consent form. The subject must be provided an opportunity to ask questions of the Investigator, and if required by local regulation, other qualified personnel. The Investigator must provide the subject with a copy of the consent form written in a language the subject understands. The consent document must meet all applicable local laws and provide subjects with information regarding the purpose, procedures, requirements, and restrictions of the study, along with any known risks and potential benefits associated with the IP, the available compensation, and the established provisions for maintaining confidentiality of personal, protected health information. Subjects will be told about the voluntary nature of participation in the study and must be provided with contact information for the appropriate individuals should questions or concerns arise during the study. The subject also must be told that their records may be accessed by appropriate authorities and Sponsor-designated personnel. The Investigator must keep the original, signed copy of the consent and must provide a duplicate copy to each subject according to local regulations. Following this study, the subject will return to their eye care professional for their routine eye care and contact lenses.

11 PROTOCOL AMENDMENT HISTORY

Version	Brief Description and Rationale
1	Initial Version of this document

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

12.2 References for this clinical trial

Not applicable.

13 Appendix

13.1 MYDAY Package Insert

CooperVision MyDay Soft (Hydrophilic) Daily Disposable Contact Lenses

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
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner
	See Instructions for Wearers
	Use by Date (expiration date)
LOT	Batch Code
STERILE	Sterile using Steam Heat

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

DESCRIPTION

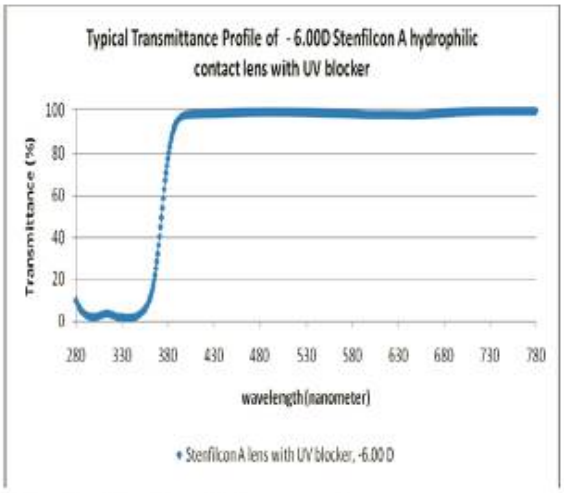
MyDay Contact Lenses are available as an Asphere, Toric, Multifocal, and Multifocal Toric lens designs.

The MyDay material stenfilcon A is primarily a random copolymer of polydimethylsiloxane methacrylate and vinylmethyl acetamide. The UV blocker used is a benzotriazolyl methacrylate. The lenses have a blue tint which is added to make the lens more visible for handling. The lenses also contain a UV absorbing monomer which is used to block UV radiation.

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing goggles or sunglasses because they do no completely cover the eye and the surrounding area. You should continue to use absorbing eyewear as directed.

Long term exposure to the 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 the outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

The MyDay (stenfilcon A) Soft (Hydrophilic) Contact Lens (-6.00 D) blocks 86% of UVA radiation and 97% UVB radiation average across the spectrum. The radiation blockage of the MyDay (stenfilcon A) lens will increase for thicker lenses (Please refer to accompanying transmittance curve graph).



MyDay (stenfilcon A) contact lenses parameters:
- Chord Diameter: 13.0 mm to 15.5mm
- Base Curve: 8.4 ± 0.5 mm and 8.7 ± 0.5 mm
- Center Thickness: 0.08 mm to 0.218 mm (varies with power)
- Powers: –20.00D to +20.00D
- Cylinder Powers: -0.25D to -10.00D
- Axis: 0° to 180° in 10° increments
- Add Power Range: +.50 to +4.00

The physical/optical properties of the lens are:
- Specific Gravity 1.033
- Refractive Index: 1.401
- Light Transmittance: 96%
- Surface Character Hydrophilic
- Water Content 54%
- Oxygen Permeability $80x10^{-11}$ $[(cm^2/sec)x(ml\ O_2)/(ml\ x\ mm\ Hg)]$

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

ACTIONS

When placed on the cornea in its hydrated state, the **MyDay** Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina.

INDICATIONS FOR USE

Aspherical

MyDay ASPHERE 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 -20.00D to +20.00D 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: MyDay (stenfilcon A) Toric 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 -10.00 diopters.

Multifocal: MyDay (stenfilcon A) MULTIFOCAL Soft Contact 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. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

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Multifocal Toric: MyDay (stenfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-dieseased eyes who may have -10.00 diopters of astigmatism or less.

CONTRAINDICATIONS (REASONS NOT TO USE):

Do not use the **MyDay** 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.
- 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

Patients should be advised of the following warnings pertaining to contact lens wear:

- PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that patients follow their eye care practitioner's directions and all labeling instructions for proper use of lenses. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**. Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the 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. If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eyecare practitioner.

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 aspheric 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 **MyDay** 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 safety precautions:

- Always discard disposable lenses after the recommended wearing schedule prescribed by the Eye Care Practitioner.
- The compatibility of the lens with lens care regimens has not been evaluated.
- Do not use saliva or any solutions for lubricating or wetting lenses.
- 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.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Instructions for **MyDay** contact lenses and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing the lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with fingernails.
- 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 a storage case and contact the eye care practitioner. Daily disposible lenses should not be reinserted. 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 **MyDay** contact lenses. For a detailed description of the fitting techniques, refer to the **MyDay** Professional Fitting and Information Guide, copies of which are available from:

CooperVision, Inc.
www.coopervision.com

WEARING SCHEDULE

The wearing schedule 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 **MyDay** lenses be discarded and replaced with a new lens on a daily basis.

DAILY DISPOSABLE WEAR: (less than 24 hours, while awake).

The maximum suggested wearing time is 12 hours:

LENS CARE DIRECTIONS

The MyDay (stenfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear single use only.. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

For MyDay contact lenses prescribed for daily wear single use only: The Eye Care Professional should review with patients that no cleaning or disinfection is needed. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

Eye care practitioners should review with the patient lens care directions, including basic lens care information in accordance with patients lens type and wearing schedule.

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or any solutions for lubricating or rewetting. Do not put lenses in the mouth.
- The patient should always have a spare pair of lenses at all times.
- Eye care practitioners may recommend a lubrication/rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If any **MyDay** lens is exposed to air while off the eye, it may become dry and brittle. In this event, simply dispose of the lens and replace with a fresh one.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues more than 5 minutes, the patient should immediately consult the eye care practitioner.

EMERGENCIES

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

HOW SUPPLIED

Each lens is supplied sterile in a blister containing buffered saline solution. The blister is labeled with the base curve, diameter, dioptic power, manufacturing lot number, and expiration date of the lens.

DO NOT USE IF THE BLISTER IS BROKEN OR THE SEAL HAS BEEN DAMAGED

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing any **MyDay** contact lens or experienced with the lenses should be reported to:

Product Services
(800) 341-2020
www.coopervision.com

CooperVision™

CooperVision, Inc.
6150 Stoneridge Mall Road
Suite 370
Pleasanton, CA 94588

Date/Time (mm/dd/yyyy GMT):	Signed by:	Justification:
03/04/2017 00:05:07	[redacted]	[redacted]
03/06/2017 14:59:19	[redacted]	[redacted]
03/07/2017 03:02:55	[redacted]	[redacted]