

AVAIRA VITALITY (fanfilcon A)

**AVAIRA VITALITY Sphere
AVAIRA VITALITY Asphere
AVAIRA VITALITY Toric
AVAIRA VITALITY Multifocal
AVAIRA VITALITY Multifocal Toric**

DAILY WEAR

SOFT (HYDROPHILIC) CONTACT LENSES

PRACTITIONER FITTING GUIDE

Table of Contents

LENS FORM AND CHARACTERISTICS	3
LENS PARAMETERS AVAILABLE	3
AVAIRA VITALITY MULTIFOCAL	4
AVAIRA VITALITY MULTIFOCAL TORIC	4
FITTING CONCEPT	4
PATIENT SELECTION.....	4
ACTIONS.....	4
INDICATIONS (USES)	4
CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS.....	5
PLEASE REFER TO THE PACKAGE INSERT IN THE BACK OF THIS GUIDE.	5
AVAIRA VITALITY FITTING PROCEDURE.....	5
FITTING SUMMARY	9
PATIENT MANAGEMENT AND FOLLOW-UP CARE	10
CLINICAL ASSESSMENT	11
MONOVISION FITTING GUIDELINES	12
CARE OF LENSES	15
PLEASE REFER TO THE “LENS CARE DIRECTIONS” SECTION OF THE PACKAGE INSERT.....	15
PATIENT CARE OF LENSES.....	15
HOW SUPPLIED.....	15
REPORTING ADVERSE REACTIONS	16
PACKAGE INSERT	17

LENS FORM AND CHARACTERISTICS

The AVAIRA VITALITY (fanfilcon A) SPHERE/ASPHERE, AVAIRA VITALITY (fanfilcon A) TORIC, AVAIRA VITALITY (fanfilcon A) MULTIFOCAL, and AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC Soft (Hydrophilic) Contact Lens is a hemispherical flexible shell that covers the cornea and extends slightly beyond the limbus, covering a portion of the adjacent sclera. In the hydrated state, the lens tends to conform to the curvatures of the anterior eye.

The lens material, when hydrated, consists of the AVAIRA VITALITY (fanfilcon A) lens material that is 55% water by weight when immersed in buffered saline. The material has a refractive index of 1.398 and the lens has a visible light transmittance of 98%. The oxygen permeability of the material at 35°C is 90×10^{-11} (cm²/sec)(ml O₂/ml x mm Hg) determined by the coulometric method.

The hydrophilic properties of the AVAIRA VITALITY SPHERE/ASPHERE, AVAIRA VITALITY TORIC, AVAIRA VITALITY MULTIFOCAL, and AVAIRA VITALITY MULTIFOCAL TORIC Soft (Hydrophilic) Contact Lens require that it be maintained in a fully hydrated state, in a solution having a tonicity compatible with tears. The lens material is stable, has good mechanical strength, and is elastic in its hydrated state. If the lens dries out, it will become hard and appear somewhat warped, then it is advised to discard the lens.

The AVAIRA VITALITY SPHERE/ASPHERE, AVAIRA VITALITY TORIC, AVAIRA VITALITY MULTIFOCAL and AVAIRA VITALITY MULTIFOCAL TORIC Soft (Hydrophilic) Contact Lenses are a hemispherical flexible shell, which covers the cornea and may cover the sclera.

LENS PARAMETERS

AVAIRA VITALITY SPHERE/ASPHERE

Diameter	13.5 to 15.0 mm
Base Curve	8.2 to 9.2 mm
Power	-20.00 D TO +20.00 D; +0.25 D steps

AVAIRA VITALITY TORIC

Diameter	13.5 to 15.0 mm
Base Curve	8.2 to 9.2 mm
Power	-20.00 D TO +20.00 D; +0.25 D steps
Cylinder Power	-0.25 D to -10.00 D
Axis	0° to 180° in 10° increments

AVAIRA VITALITY MULTIFOCAL

Diameter	13.5 to 15.0 mm
Base Curve	8.2 to 9.2 mm
Power	-20.00D to +20.00D
Add	+0.25 D to +4.00 D

AVAIRA VITALITY MULTIFOCAL TORIC

Diameter	13.5 to 15.0 mm
Base Curve	8.2 to 9.2 mm
Power	-20.00 D to +20.00 D
Cylinder Power	-0.25 D to -10.00 D
Axis	0 ⁰ to 180 ⁰ in 10 ⁰ increments
Add	+0.25 D to +4.00 D

FITTING CONCEPT

The fitting concept is based on the draping effect of a high water content lens. Various base curves are achieved when the peripheral portion of the AVAIRA VITALITY (fanfilcon A) SPHERE/ASPHERE, AVAIRA VITALITY (fanfilcon A) TORIC, AVAIRA VITALITY (fanfilcon A) MULTIFOCAL, and AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC Soft (Hydrophilic) Contact Lens flexes to the curvature of the cornea. The water content of the lens combined with thin lens sections permits excellent draping across a broad range of corneal curvatures.

The draping effect of the lens automatically adjusts to the sagittal height for each cornea. The lens parallels the apex of the cornea providing broad apical contact of the central cornea, vaulting or “clearance” of the limbus and light scleral bearing.

PATIENT SELECTION

An examination, including history, refraction, keratometry, biomicroscopy, and other pertinent tests and measurements should be performed. If the patient has the necessary qualifications and no contraindications exist, the patient may be considered for fitting.

ACTIONS

When placed on the human cornea, the AVAIRA VITALITY (fanfilcon A) Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina.

INDICATIONS (Uses)

Sphere/Asphere: AVAIRA VITALITY SPHERE and ASPHERE (fanfilcon 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: AVAIRA VITALITY (fanfilcon 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: AVAIRA VITALITY (fanfilcon A) MULTIFOCAL Soft 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 +0.25 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.

MULTIFOCAL TORIC: AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have -10.00 diopters of astigmatism or less.

Eye Care Practitioners may prescribe the Avaira Vitality (fanfilcon A) Soft Contact lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement or single-use disposable wear.

When prescribed for frequent/planned replacement, the Avaira Vitality (fanfilcon A) Soft Contact lens is to be cleaned, rinsed, and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only.

When prescribed for single-use disposable wear, the Avaira Vitality (fanfilcon A) Soft Contact lens is to be discarded after each removal.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS

Please refer to the Package Insert in the back of this guide.

AVAIRA VITALITY FITTING PROCEDURE

- Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear as described in the Package Insert.
- Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
- Place the lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variation in the tonicity, pH of the lens solutions and individual tear composition may cause slight changes in fitting characteristics.
- The lens should cover the patient's cornea fully, provide discernible movement (0.10 mm to 1.00 mm) after blink, be comfortable for the patient and provide satisfactory visual performance.
- Full coverage of the cornea is defined as the lens edge extending beyond the limbus area in all directions. Initial lens evaluation must be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.

- Following a blink the lens should move vertically on the patient’s eye about 0.10 mm to 1.00 mm.
- When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and the Patient Information Booklet.

AVAIRA VITALITY (fanfilcon A) TORIC LENS DESIGN

The AVAIRA VITALITY (fanfilcon A) TORIC lenses are designed to have an improved thickness and ballast arrangement and a more effective interaction between the stabilization mechanism and the eyelid of the wearer during blinking.

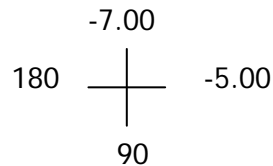
AVAIRA VITALITY (fanfilcon A) TORIC FITTING PROCEDURE

1. Determine Patient’s Power Requirements:
 - Convert the patient’s spectacle Rx to minus cylinder form.
 - The sphere and cylinder power of the contact lens prescription is the same as the spectacle Rx when the power is less than 4.00 D in both meridians. When the power is greater than or equal to 4.00 D, vertex the prescription to the spectacle plane.

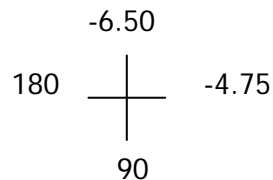
(See **EXAMPLE**) to determine the most appropriate axis.

EXAMPLE: History of nasal rotation on eye being fit

OD Spectacle Rx: -5.00 -2.00 x 180



OD Contact Lens Rx: -4.75 -1.75 x 180



Clinical experience has shown that the initial spherical and cylindrical power may vary by +/- 0.25 diopters and the axis of the initial lens may vary by 5 degrees on cylinders up to 2.00 diopters and 3 degrees for cylinders over 2.00 diopters without diminishing visual acuity of the patient. If you wish, call CooperVision’s Consultation Department with the patient’s spectacle Rx and central K readings and they will make the proper compensations for your AVAIRA VITALITY Rx.

2. Equilibration:
 - Allow approximately 15 minutes for the trial lenses to fully equilibrate after insertion, before evaluation of fit and vision.

3. Check Lens Fit:

A properly centered lens will provide complete corneal coverage at all times. Decentration which leaves 0.50 mm or less of the lens extending onto the sclera in any position will likely result in decreased or fluctuating vision.

The diameter of the lens should be such that the lens extends past the limbus 1.0-2.0 mm on both the nasal and temporal sides of the cornea.

Movement of the lens with blinking is important to maintain optimum corneal physiology. The lens should move 0.50-1.5 mm when the patient blinks and lag 0.50-1.5 mm in upward gaze. While some patients may be able to maintain adequate corneal health with less movement, tight lenses should be avoided. If the lens is exhibiting minimal movement, apply a slight amount of digital pressure against the lower lid. The lens should move freely and easily, and return to the centered position when released. A tight lens will resist movement.

4. To Determine the Optimum Power and Axis for the Final Lens:

- Measure the amount of lens rotation, if any. Be sure the eye for which lens rotation is being evaluated is sighting straight ahead (i.e., down the optic axis of the slit lamp), as parallax resulting from misalignment can yield inaccurate measurements.
- If acuity is less than desired, do a complete over-refraction to include sphere, cylinder and axis and call CooperVision's Consultation Department with the following information:
 - Contact lens parameters
 - Over-refraction (sphere, cylinder and axis) and visual acuity
 - Any lens rotation

5. When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and the Patient Information Booklet.

AVAIRA VITALITY (fanfilcon A) MULTIFOCAL LENS DESIGN

Presbyopia Needs Assessment

Multifocal contact lenses may produce compromise to vision under certain circumstances and the patient should understand that they might not find their vision acceptable in specific situations (i.e. reading a menu in a dimly lit restaurant, driving at night in rainy/foggy conditions etc.). Therefore, caution should be exercised when the patient is wearing the correction for the first time until they are familiar with the vision provided in visually challenging environments. Occupational and environmental visual demands should be considered. If the patient requires critical visual acuity and stereopsis, it should be determined by trial whether this patient can function adequately with the Biofinity Multifocal contact lenses for the correction of presbyopia. Biofinity Multifocal contact lenses for the correction of presbyopia may not be optimal for such activities as:

1. Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

2. Driving automobiles (e.g. driving at night). Patients need to ensure they meet state driver's license requirements and should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

Avaira Vitality Multifocal contact lenses for the correction of presbyopia are not recommended for patients who have 2.00D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise.

The AVAIRA VITALITY (fanfilcon A) MULTIFOCAL lenses are an optical system that consists of complementary lenses which allows for correction of presbyopia in persons who are myopic or hyperopic.

The Dominant and Non Dominant eyes shall each be fitted with concentric aspheric or multiple curve presbyopia correcting design. Design options may include central distance OR central near optical designs. The designs are optically smooth and continuous. There is no pupil size requirement in order to benefit from the Multifocal correction.

Depending on the fitting requirements of the final product and the requirements for the individual patient, considering Add power etc., the Dominant and Non Dominant eyes may be fitted with:

- a) A matched multiple curve, presbyopia correcting design in each eye, with or without optical defocus for the non-dominant eye
- b) Unmatched multiple curve, presbyopia correcting designs in each eye, with or without optical defocus for the non-dominant eye

AVAIRA VITALITY (fanfilcon A) MULTIFOCAL FITTING PROCEDURE

1. Determine the required Additional Distance and Near Power by performing a near full refraction.
2. Select the AVAIRA VITALITY (fanfilcon A) Multifocal lens that corresponds to the patient's spherical equivalent prescription corrected to the corneal plane for distance and the patients Addition Power.
3. After the lenses have settled on the eye check distance visual acuity, near visual acuity and perform an over-refraction, if required to optimize distance and near visual acuity.

AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC LENS DESIGN

Prior to fitting any multifocal lens, consider the recommendations ***Presbyopia Needs Assessment*** above.

The AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC lenses contain a multiple-curve, presbyopic correcting design. The posterior surface has a toric generated surface for the purpose of correcting vision in an eye that is astigmatic.

The Dominant and Non Dominant eyes shall each be fitted with a concentric aspheric or multiple curve presbyopia correcting design. Design options may include central distance OR central near optical designs. The designs are optically smooth and continuous. There is no pupil size requirement in order to benefit from the Multifocal correction.

Depending on the fitting requirements of the final product and the requirements for the individual patient, considering Add power etc., the Dominant and Non Dominant eyes may be fitted with:

- a) A matched multiple curve, presbyopia correcting design in each eye, with or without optical defocus for the non-dominant eye
- b) Unmatched multiple curve, presbyopia correcting designs in each eye, with or without optical defocus for the non-dominant eye

AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC FITTING PROCEDURE

1. Refer to AVAIRA VITALITY (fanfilcon A) TORIC FITTING PROCEDURE above for toric fitting guidance.
2. Determine the required Additional Distance and Near Power by performing a near full refraction.
3. Select the Avaira Vitality (fanfilcon A) Multifocal lens that corresponds to the patient's spherical equivalent prescription corrected to the corneal plane for distance and the patients Addition Power.
4. After the lenses have settled on the eye check distance visual acuity, near visual acuity and perform an over-refraction, if required to optimize distance and near visual acuity.

FITTING SUMMARY

Fitting performance and visual response should be confirmed with the prescription lenses prior to dispensing and the management of certain adaptive symptoms should be discussed with the patient prior to dispensing.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight eye redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these mild symptoms will disappear. If these symptoms persist, the patient should be instructed to contact their Eye Care Practitioner.

During the first few weeks of lens wear, patients may report a small amount of secretions on their eyelids, hazy vision on awakening and occasional dryness of the eyes during the day. These symptoms are minor and may be alleviated by using a lubricating/re-wetting solution.

PATIENT MANAGEMENT AND FOLLOW-UP CARE

1. Dispensing Visit

The lenses are delivered sterile, immersed in buffered saline solution, and supplied in a blister pack. Insertion and removal is done in the conventional manner used for soft hydrophilic contact lenses.

Evaluate patient's lenses on the eyes for physical fit as described in the preceding discussion. Instruct the patient on the technique for soft lens insertion and removal, as well as all aspects of lens care, including cleaning, disinfection, storage, and handling. Dispense to the patient written instructions on lens care and a copy of the AVAIRA VITALITY SPHERE/ASPHERE, AVAIRA VITALITY TORIC, AVAIRA VITALITY MULTIFOCAL or AVAIRA VITALITY MULTIFOCAL TORIC Soft (Hydrophilic) Contact Lens Patient Instruction Booklet. Review these instructions carefully with your patient.

2. Recommended Wearing Schedule

The AVAIRA VITALITY (fanfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear.

When prescribed for Frequent Replacement wear, patients are instructed to disinfect the lenses as directed by their Eye Care Practitioner.

It is recommended that a contact lens-wearing patient see his or her EyeCare Practitioner twice each year or, if so directed, more frequently.

Daily wear: Patients tend to over wear the lenses initially. Therefore, practitioners should stress to these patients the importance of adhering to a proper initial daily wearing schedule.

3. Follow-Up Care

Follow-up care includes routine periodic progress examinations, management of specific problems, if any, and review of proper lens care and handling. Barring complications, the recommended schedule of follow-up examinations should be:

Daily Wear

- a. One week post-dispensing
- b. One month after dispensing
- c. Three months after dispensing
- d. Every six months thereafter

4. Procedures and Instrumentation for Follow-Up Visits (with lenses on, preferably for at least six hours)

- a. Record patient's symptoms, if any.
- b. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- c. Check visual acuity and refract over lens.
- d. Check for residual astigmatism with the aid of a refractor or loose trial lenses (do not use auto-refractor).

e. **Biomicroscopy:**

- i. Examine the conjunctiva and lids.
- ii. Check for lens edge impingement of the sclera, indentation, or vessel blanching, using low to medium magnification.
- iii. Check integrity of lens edges.
- iv. Check for surface deposits, deep scratches or edge nicks.

5. Procedures for Follow-Up Visits (with lenses removed):

- a. Perform a biomicroscopic examination of the cornea and limbus, both with and without the use of fluorescein; check for edema, injection, vascularization, corneal staining, or any indication of iritis.
- b. Measure corneal curvatures with keratometer and compare to original values and mire quality. Any deviations from baseline (pre-fit) should be noted.
- c. Check for spectacle blur shortly after lenses are removed. Record all measurable values and any remarkable findings.

If any of the above observations are judged to be abnormal, professional judgment is to be used in alleviating the problem and restoring the eye to optimal conditions. If the criteria for a well-fitted lens are not reached during any follow-up examinations, the patient's fitting procedure should be repeated. The patient should be refitted, with necessary follow-up examinations also repeated.

CLINICAL ASSESSMENT

1. Criteria of a Well-Fitted Lens

A well-fit AVAIRA VITALITY (fanfilcon A) SPHERE/ASPHERE, AVAIRA VITALITY (fanfilcon A) TORIC, AVAIRA VITALITY (fanfilcon A) MULTIFOCAL, and AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC Soft (Hydrophilic) Contact Lens best satisfies the following criteria:

- Full corneal coverage.
- Good centration (concentric about the visible iris).
- Satisfactory lens sag (in up gaze 0.10 to 1.00mm is ideal) with the blink.
- The lens moves freely when manipulated with digital pressure against the lower lid.
- Satisfactory comfort response by the patient.
- Satisfactory vision response by the patient.

2. Characteristics of a Tight (Steep) Lens

A tight AVAIRA VITALITY (fanfilcon A) SPHERE/ASPHERE, AVAIRA VITALITY (fanfilcon A) TORIC, AVAIRA VITALITY (fanfilcon A) MULTIFOCAL, and AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC Soft (Hydrophilic) Contact Lens would display some or all of the following characteristics:

- Good centration.
- Little or no up gaze sag.
- The lens resists movement when manipulated with digital pressure against the lower lid.
- Good comfort
- Vision may be blurred and clear immediately following blink.
- Bubble(s) under the lens.
- Conjunctival indentation and/or blanching of limbal vessels at the lens edge.
- Limbal-conjunctival hyperemia.

3. Characteristics of a Loose (Flat) Lens

A loose AVAIRA VITALITY (fanfilcon A) Soft (Hydrophilic) Contact Lens would display some or all of the following characteristics:

- Decentration (usually temporally and/or superiorly).
- Excessive up gaze sag.
- Reduced comfort response-usually lower lid sensation.
- Lens edge standoff.
- Unstable vision.

MONOVISION FITTING GUIDELINES

1. Patient Selection

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 0.75 diopter) in one eye may not be a good candidate for monovision with the AVAIRA VITALITY (fanfilcon A) Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

- (1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- (2) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

B. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "sight eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

C. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

D. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near:

Example:

A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left with a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions:

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
 - Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
 - Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.
- * The decision to fit a patient with a monovision correction is most appropriately left to the Eye Care Practitioner in conjunction with the patient after carefully considering the patient's needs.
- * All patients should be supplied with a copy of the Patient Instruction manual.

CARE OF LENSES

Please refer to the "Lens Care Directions" section of the Package Insert.

PATIENT CARE OF LENSES

Please refer to the Package Insert and the Patient Information Booklets for information pertaining to Cleaning/Disinfecting, Lens Care, and Handling Instructions.

HOW SUPPLIED

Each lens is supplied sterile in a blister containing buffered saline solution. The blisters are packed in boxes. The following information is provided: the base curve, diameter, dioptric power, manufacturing lot number of the lens and the expiration date of the product.

REPORTING ADVERSE REACTIONS

All serious adverse experiences and adverse reactions in patients wearing the AVAIRA VITALITY (fanfilcon A) Soft (Hydrophilic) Contact Lens or experienced with the lenses should be reported to:



Attn: Product Services
711 North Road
Scottsville, New York 14546
USA
(800) 341-2020
www.coopervision.com






**CooperVision AVAIRA VITALITY Soft (Hydrophilic) Daily Wear
Soft Contact Lenses**

Package Insert

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
	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)
	Batch Code
	Sterile using Steam Heat

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

DESCRIPTION

AVAIRA VITALITY Contact Lenses are available as Sphere, Asphere, Toric, Multifocal, and Multifocal Toric lens designs.

The AVAIRA VITALITY material (fanfilcon A) is primarily a random copolymer of polydimethylsiloxane methacrylate and vinylmethyl acetamide. 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, benzotriazolyl methacrylate, which is used to block UV radiation.

AVAIRA VITALITY (fanfilconA) SPHERE AND ASPHERE contact lenses parameters:

- o Diameter: 13.5 mm to 15.0 mm
- o Base Curve: 8.2 mm to 9.2 mm
- o Center Thickness: 0.06 mm to 0.6 mm (varies with power)
- o Powers: -20.00 D to +20.00 D
- o D

AVAIRA VITALITY (fanfilconA) TORIC contact lenses parameters:

- o Diameter: 13.5 mm to 15.0 mm
- o Base Curve: 8.2 mm to 9.2 mm
- o Center Thickness: 0.06 mm to 0.6 mm (varies with power)
- o Powers: -20.00 D to +20.00 D
- o Cylinder Powers: -0.25 D to -10.00 D
- o Axis: 0° to 180°

AVAIRA VITALITY (fanfilconA) MULTIFOCAL contact lenses parameters:

- o Diameter: 13.5 mm to 15.0 mm
- o Base Curve: 8.2 mm to 9.2 mm
- o Center Thickness: 0.06 mm to 0.6 mm (varies with power)
- o Powers: -20.00 D to +20.00 D
- o Add Power Range: +.25 D to +4.00 D

AVAIRA VITALITY (fanfilconA) MULTIFOCAL TORIC contact lenses parameters:

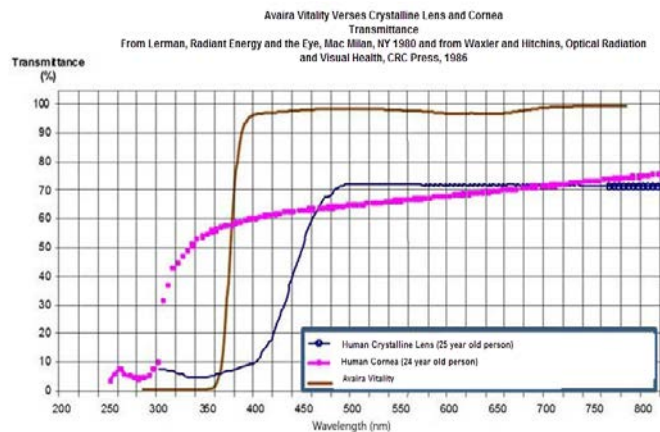
- o Diameter: 13.5 mm to 15.0 mm

- Base Curve: 8.2 mm to 9.2 mm
- Center Thickness: 0.06 mm to 0.6 mm (varies with power)
- Powers: -20.00 D to +20.00 D
- Cylinder Powers: -0.25 D to -10.00 D
- Axis: 0° to 180°
- Add Power Range: +.25 D to +4.00 D

The physical/optical properties of the lens are:

- Specific Gravity 1.026
- Refractive Index: 1.398 ± 0.005
- Light Transmittance: 98% +2/-5%
- Surface Character Hydrophilic
- Water Content 55% ± 2%
- Oxygen Permeability $90 \times 10^{-11} [(cm^2/sec) \times (ml O_2) / (ml \times mm Hg)]$

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



1. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
2. Waxler M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 10, figure 5

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 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 AVAIRA VITALITY (fanfilcon A) Soft (Hydrophilic) Contact Lens (-6.00 D) blocks >90% of UVA radiation and >99% UVB radiation average across the spectrum. The radiation blockage of the AVAIRA VITALITY soft contact lens will increase for thicker lenses.

ACTIONS

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

INDICATIONS FOR USE

Sphere/Asphere: AVAIRA VITALITY SPHERE and ASPHERE (fanfilcon 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: AVAIRA VITALITY (fanfilcon 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: AVAIRA VITALITY (fanfilcon A) MULTIFOCAL Soft 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 +0.25 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.

Multifocal Toric: AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes in powers of -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatism corrections from -0.25 to -10.00 diopters.

Eye Care Practitioners may prescribe the Avaira Vitality (fanfilcon A) Soft Contact lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement or for single-use disposable wear.

When prescribed for frequent/planned replacement, the Avaira Vitality (fanfilcon A) Soft Contact lens is to be cleaned, rinsed and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only.

When prescribed for single-use disposable wear, the Avaira Vitality (fanfilcon A) Soft Contact lens is to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE):

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

- o Acute and subacute inflammation or infection of the anterior chamber of the eye.
- o Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- o Severe insufficiency of lacrimal secretion (dry eyes).
- o Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic.
- o Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- o Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses.
- o Allergy to any ingredient, such as mercury or thimerosal, in a solution, which is to be used to care for any AVAIRA VITALITY lens.
- o Any active corneal infection (bacterial, fungal, or viral).
- o If eyes become red or irritated.
- o 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 professional 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 (professional) 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 study¹ 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 wearers see their Eye Care Practitioner routinely as directed.

¹NewEnglandJournalofMedicine,September21,1989;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 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 **AVAIRA VITALITY** 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.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- 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 **AVAIRA VITALITY** 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. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears damaged, the patient should thoroughly clean, rinse, and disinfect the 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 **AVAIRA VITALITY** contact lenses. For a detailed description of the fitting techniques, refer to the **AVAIRA VITALITY** Professional Fitting and Information Guide, copies of which are available from:

CooperVision, Inc.
711 North Road
Scottsville, NY 14546
1-800-341-2020
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 **AVAIRA VITALITY** 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 walking 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.

LENS CARE DIRECTIONS

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.

General Lens Care: (For Frequent Replacement Lenses Only) Basic Instructions:

- This section is NOT applicable for daily wear disposable lenses.
- Always use fresh, unexpired lens care solutions.
- Use the recommended chemical (not heat) system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Lenses should be cleaned, rinsed, and disinfected each time they are removed.
- Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- Always remove, clean, rinse, (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribed by the Eye Care Practitioner. The use of an enzyme cleaner is not recommended.
- The eye care practitioner should recommend a care system that is appropriate for AVAIRA VITALITY contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow directions.

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfection solution to remove cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, and rinsing, disinfect lenses using the system recommended by the manufacturer and/or Eye Care Practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the Eye Care Practitioner for information on the storage of lenses. After removing the lenses from the lens case, empty, and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the lens case is used again, refill it with storage solution. Replace the lens case at regular intervals as recommended by the lens case manufacturer or your Eye Care Practitioner.
- 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.

CHEMICAL LENS DISINFECTION (Including Hydrogen Peroxide – For Frequent Replacement Lenses Only):

- This section is NOT applicable for daily wear disposable lenses.
- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution. After cleaning and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the eye care regimen recommended by the lens manufacturer or the Eye Care Practitioner.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- CAUTION: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement in the eye should reduce the potential for irritation.
- When using hydrogen peroxide lens care systems, the patient should be instructed to **use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution.** The patient should be advised that failure to use the specialized case will result in severe stinging, burning, and injury to the eye. The patient should be instructed to follow the recommendations on the hydrogen peroxide system labeling exclusively. Following disinfection with a peroxide system, the lenses should be rinsed with sterile saline.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, and rinsed with solution recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the Eye Care Practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If any **AVAIRA VITALITY** 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, and the presence of a UV-blocker is noted. When applicable, the lens is also labeled with the add power, cylinder power and cylinder axis.

***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 **AVAIRA VITALITY** contact lens or experienced with the lenses should be reported to:



CooperVision™

Attn: Product Services
711 North Road
Scottsville, New York 14546
(800) 341-2020

www.coopervision.com

Revision Date: March 2016
Part Number:PI01000
Revision: A