OCuSOFT®

AMENITY™

PROFESSIONAL FITTING GUIDE

OCuSOFT® Amenity™

(linofilcon A) Daily Disposable Contact Lenses with HydraSeal™

℞ ONLY

CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.

PROFESSIONAL FITTING GUIDE

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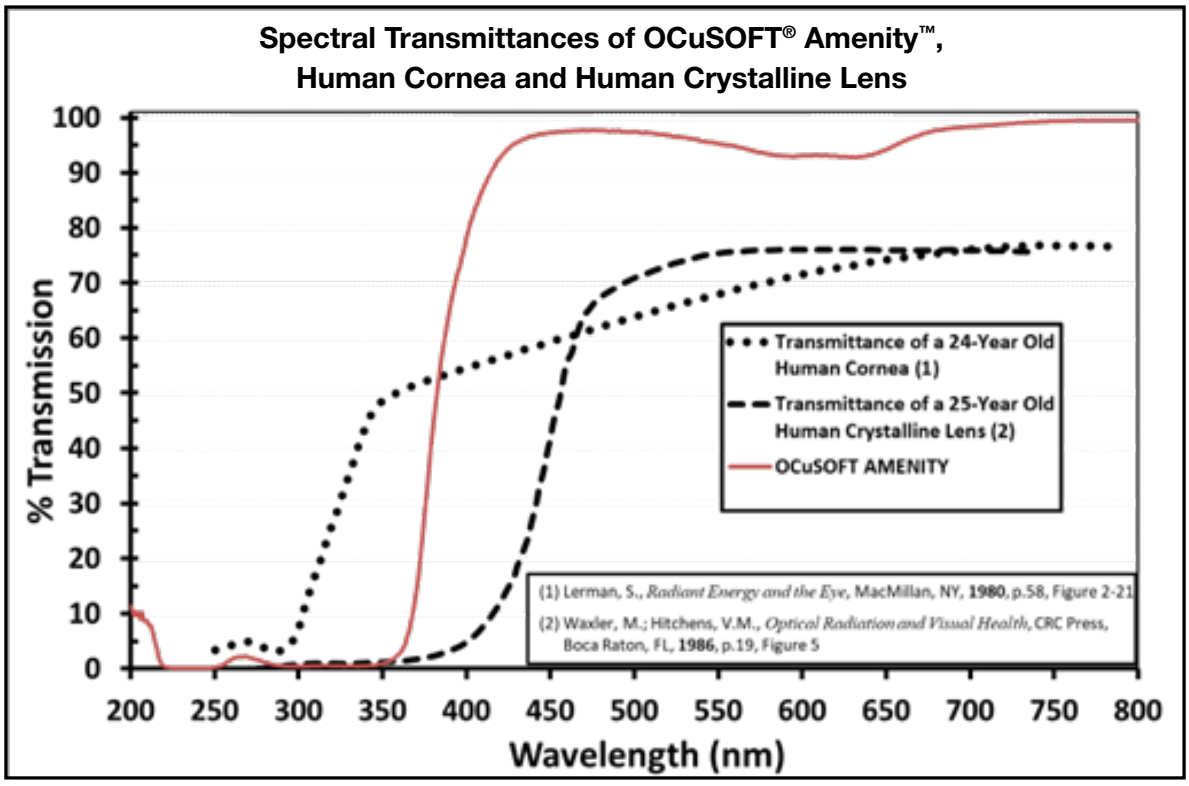
DESCRIPTION

The OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are a hemispherical shells with molded spherical base curves and molded front surfaces. The hydrophilic characteristics allow aqueous solutions to enter the lenses. The lenses are fabricated from linofilcon A, which is a random co-polymer of silicone containing monomers and hydrophilic monomers. The lens consists of 62.0% linofilcon A and 38.0% water by weight when immersed in saline solution. The linofilcon A name has been adopted by the United States Adopted Names Council (USAN).

The OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ contain C.I. Reactive Blue No. 19 (21 CFR Part 73.3127) for visibility and handling.

The OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ incorporates a benzotriazole UV blocking monomer to help protect against transmission of harmful UV radiation. The lens blocks >95% in the UVB range (280nm - 315nm), and >70% in the UVA range (316nm - 380nm). Refer to the following transmittance profile for the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™:



Note: the above % transmission data are based on measurements from a -3.00 D lens. The data was obtained from measurements with a spectrophotometer taken through the central 3-5 mm portion of the lens.

The following table lists the material properties and available parameters for the **OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™.**

Parameter	Range	Tolerance*
Chord Diameter	13.00 mm to 15.00 mm	±0.20 mm
Center Thickness	0.080 mm @ -3.00 D	When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5%
Base Curve	8.00 mm to 9.50 mm	±0.20 mm
Back Vertex Power (F'v)	+20.00D to -20.00D	When 0.00 < |F'v| ≤ 10.00 D → ±0.25 D When 10.00 < |F'v| ≤ 20.00 D → ±0.50 D
Cylinder Power (F'c)	-0.25 D to -2.25 D (in 0.25 D steps)	When 0.00 < |F'c| ≤ 2.00 D → ±0.25 D When 2.00 < |F'c| ≤4.00 D →±0.37 D
Cylinder Axis	10° to 180° in 10° steps (in 10° steps)	When 0.00 < |F'c| ≤ 1.50 D → ± 8° When |F'c| > 1.50 D →± 5°
Multifocal Power	+0.25 D to +4.00 D (in 0.25 D steps)	±0.25D
Surface Appearance	-	Lenses should be clear with no surface defect
Oxygen Permeability (x 10-11(cm2/sec)(mlO2)/(ml x mmHg))	100	±20%
Light Transmittance - Tinted (@ 380-780nm)	95%	±5%
Ultraviolet Radiation Transmittance	< 5 % TUVB < 30 % TUVA	T_{UVB} (280 to 315 nm) < 0.05T_V T_{UVA} (316 to 380 nm) < 0.50T_V
Water Content	38%	±2%
Refractive Index	1.415 (hydrated)	±0.005

**ANSI Z80.20, Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties (2016)*

ACTIONS

In the hydrated state, the **OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™** when placed on the cornea, act as refracting media to focus light rays on the retina.

INDICATIONS

OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ 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 1.00 diopters or less that does not interfere with visual acuity.

Special Precautions for Eye Care Practitioner:
Due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material were 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, wet-ability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on the patient's ocular health must 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.

CONTRAINDICATIONS (REASONS NOT TO USE)

Please reference Contraindications (Reasons Not to Use) in the Package Insert included at the end of this Fitting Guide.

WARNINGS

Please reference Warnings in the Package Insert included at the end of this Fitting Guide.

PRECAUTIONS

Please reference Precautions in the Package Insert included at the end of this Fitting Guide.

ADVERSE REACTIONS

Please reference Adverse Reactions in the Package Insert included at the end of this Fitting Guide.

PATIENT SELECTION

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ should not be provided with this lens. All necessary steps in lens care and all precautions and warnings should be discussed and understood by the patient (Review Package Insert with patient).

FITTING PROCEDURE

- Pre-Fitting Examination
- Initial Lens Power Selection
- Initial Lens Diameter and Base Curve Selection
- Initial Lens Evaluation
- Follow-Up Care

PRE-FITTING EXAMINATION

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

- Determine whether a patient is a suitable candidate for daily wear contact lenses (refer to contraindications).
- Collect and record baseline clinical information to which post-fitting examination results can be compared.
- Make ocular measurements for initial contact lens parameter selection.

INITIAL LENS POWER SELECTION

- Convert the spectacle Rx to minus cylinder forms.
- Compensate the spectacle Rx for vertex distance if the power is greater then + or – 4.00 diopters.
- Drop the cylinder.
- Add +0.25 diopter to compensate for minus tear lens.
- If refractive astigmatism exceeds 0.75 diopter, determine equivalent sphere and then compensate for power by adding +0.25 diopter for minus tear lens.

INITIAL LENS DIAMETER & BASE CURVE SELECTION

The lens is currently offered in one diameter (14.2 mm) and one base curve (8.6 mm).

INITIAL LENS EVALUATION

- Check Lens Centration, Movement, and Size:

  The criteria for a well fit lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.5 millimeters, lags downward about 1 to 2 millimeters on upward gaze, and does not move excessively as a result of blinking or exaggerated eye movements.

  After the trial lens settled on the eye (5–10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with the slightest pressure and return to the centered position when released.

  Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1–2 millimeters.

- Refract Over the Lens and Determine Visual Acuity:

  Allow approximately 10 minutes for fluid equilibration and patient adaptation prior to over refracting. Determine best visual acuity when final over refraction has been achieved. If good visual acuity cannot be obtained through the lens with spherocylindrical over refraction, re-evaluation of the physical fit should be considered. Trial lens procedure should be repeated with lenses of different base curves.

- Determine the Optical Power for the Lens Selected:

  When the proper physical fit has been determined, covert the over refraction through the diagnostic lens to equivalent sphere and add this to the power of the train lens. This will provide the final power of the lens.

FOLLOW-UP CARE

- Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear.
- Prior to a follow-up examination, the contact lenses should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- With lenses in place on the eyes, evaluate fitting performance to assure that criteria of a well-fitted lens continues to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- After the lens removal, conduct a thorough biomicroscopy examination.

  1. The presence of vertical corneal striae in the posterior central cornea and/or cornea neovascularization is indicative of excessive corneal edema.

  2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the criteria of a well-fitted lens are not satisfied during any follow-up examinations, the patient should be re-fitted with a more appropriate lens.

CLINICAL ASSESSMENT

1. Critera of a Well-Fitted Lens
   The criteria of a well fitted lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.5 millimeters, lags downward about 1 to 2 millimeters on upward gaze, and does not move excessively as a result of blinking or exaggerated eye movements.

   After the trial lens settled on the eye (5–10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with the slightest pressure and return to the centered position when released.

   Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1–2 millimeters

2. Characteristics of a Tight (Steep Lens)
   A tight (steep) lens does not move easily on the cornea with slight pressure.

3. Characteristics of a Loose (Flat) Lens
   A loose (flat) lens sags more than 2.0 millimeters on upward gaze.

FOLLOW-UP EXAMINATIONS

- Within one week of lens dispensing.
- After three weeks of lens wear.
- After seven weeks of lens wear.
- After each six-month period of lens wear.

At the follow up examinations, the patient should report good subjective quality of vision. Adaptation to vision with OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ should occur almost immediately and should definitely be reported within the first (1 week) follow up visit. At these follow up visits the practitioner should:

1. Check distance and near acuity with lens in place.
2. Over-refract to verify lens prescription.
3. Observe the position of the lens on the cornea. The lens should be centered and move on upward gaze and with a blink.
4. Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
5. Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
6. Perform a slit lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates, and perilimbal injection. Reinsert the lens only after all residual Fluorescein has dissipated from the eye.

LENS CARE DIRECTIONS

Please reference Lens Care Directions in the Package Insert included at the end of this Professional Fitting Guide.

RECOMMENDED WEARING SCHEDULE

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed, and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lens. Patients tend to overwear the lens initially. It is important not to exceed the initial wearing schedule. Regular check ups, as determined by the eyecare practitioner, are also extremely important.

Studies have not been completed to show that the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are safe to wear during sleep.

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 1.50 diopter) in one eye may not be a good candidate for monovision with the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™.

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 driver's 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 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.

A. Ocular Preference Determination Methods

Method 1—determine which eye is the "sight eye". Have the patient point to and 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 latest 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.

B. 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.

C. 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 are 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 eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ Patient Instruction / Wearer's Guide.

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: Flush eyes immediately with tap water and immediately contact the eye care practitioner or visit a hospital emergency room without delay.

REPORTING OF ADVERSE REACTIONS

Practitioners should report any adverse reactions to the OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ within 5 days to OCuSOFT Inc. Additional Fitting Guides, Package Inserts and Patient Guides are available from:

OCuSOFT Inc.
30444 S.W. Freeway
Rosenberg TX 77471

HOW SUPPLIED

OCuSOFT® Amenity™ (linofilcon A) Daily Disposable Contact Lenses with HydraSeal™ are sterile in sealed blister packages containing a buffered saline solution. The base of the package is made from polypropylene, which is covered with an aluminum foil seal on top. The blister packages are marked with the base curve, diameter, dioptric power, cylinder power, cylinder axis, multifocal add power, lens color, manufacturing lot number, and expiration date of the lens.