3. Criteria of a Steep Fitting Lens

A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation, and resistance when pushing the lens up digitally with the lower lid. If the lens is judged to be steep fitting, it should not be dispensed to the patient.

If the initial base curve is judged to be flat or steep fitting, the alternate base curve, if available, should be trial fit and evaluated after the patient has adjusted to the lens. The lens should move freely when manipulated digitally with lower lid, and then return to a properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

E. Final Lens Power (Spherical)

A spherical over-refraction should be performed to determine the final lens power after the lens fit is judged acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

Example 1:	
Diagnostic lens:	-2.00D
Spherical over-refraction:	-0.25D
Final lens power:	-2.25D

Example 2:	
Diagnostic lens:	-2.00D
Spherical over-refraction:	+0.25D
Final lens power:	-1.75D

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see dispensing and follow up information in **PATIENT MANAGEMENT**).

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download from www.acuvue.com.

MULTIFOCAL FITTING GUIDELINES

A. Presbyopic Needs Assessment & Patient Education

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 dim 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 ACUVUE® OASYS MAX 1-Day Multifocal Contact Lenses. 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 these lenses should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

These lenses are not recommended for patients who have –1.00D or greater of refractive cylinder as this level of uncorrected cylinder may lead to additional visual compromise.

These lenses are available in the following ADD powers:

- Lens "LOW" ="low" near ADD lens (Max +1.25 ADD)
- Lens "MID" = "medium" near ADD lens (Max +1.75 ADD)
- Lens "HGH" = "high" near ADD lens (Max +2.50 ADD)

B. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if necessary. Determine the spherical equivalent distance prescription for a multifocal patient. Determine the eye dominance using one of the methods below:

Method 1: Determine which eye is the "sighting 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 (preferred): Determine which eye will accept the added power with the least reduction in vision while both eyes are open. Place a hand-held trial lens equal to +1.00D 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 +1.00D lens over the right or left eye, which is the non-dominant eye.

C. Select the Initial Trial Lens

1. For each eye, select the trial lens distance power that is closest to the patient's distance spherical equivalent. Remember to compensate for vertex distance if necessary.
2. Select the near power of the lens based on the patients ADD range as follows:
   - ADD: +0.75 to +1.25 use a "LOW" near ADD lens on each eye
   - ADD: +1.50 to +1.75 use a "MID" near ADD lens on each eye
   - ADD: +2.00 to +2.50 use a "MID" near ADD on the dominant eye and a "HGH" near ADD lens on the non-dominant eye
3. Allow the lenses to settle for a minimum 10 minutes.
4. Assess distance and near vision binocularly and monocularly.
5. Demonstrate the vision under various lighting conditions (normal and decreased illumination) and at distance, intermediate and near.
6. Make adjustments in power as necessary based on the distance over-refraction. The use of hand held trial lenses is recommended. Check the impact on distance and near vision.
7. If vision is still unacceptable, make adjustments in power as necessary (see **"Multifocal Troubleshooting"** below). If distance and near vision are acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable, dispense the lenses instructing the patient to return in one week for reassessment (see PATIENT MANAGEMENT section).

D. Multifocal Troubleshooting

Unacceptable Near Vision:

If it has been determined that no change is required based on the over-refraction then add +0.25 D to the spherical power of the non-dominant eye.

Unacceptable Distance Vision:

If it has been determined that no change is required based on the over-refraction then make the changes as listed below:

- If the patient is wearing two "LOW" ADD lenses, change the dominant eye to an ACUVUE® OASYS MAX 1-Day Contact Lens sphere lens with a power equal to the spherical equivalent distance prescription.
- If the patient is wearing two "MID" ADD lenses, change the ADD power in the dominant eye to the "LOW" ADD power.
- If the patient is wearing a "MID" ADD lens in the dominant eye and a "HGH" ADD lens in the non-dominant eye, change the non-dominant eye to a "MID" ADD lens and add +0.25D to the distance power.

Once the changes have been made for the troubleshooting repeat steps 3-6 in section C above ("**Select the Initial Trial Lens**") to assess if the vision is acceptable.

E. 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 adaptational 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.

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download from www.acuvue.com.

MONOVISION FITTING GUIDELINES

A. Patient Selection

Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient with significant amounts of uncorrected astigmatism (greater than 1.00D) in one eye may not be a good candidate for monovision correction with these lenses.

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 correction. Monovision contact lens wear may not be optimal for activities such 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.

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 spectacles (multifocal, bifocal, trifocal, readers, progressives). Each patient should understand that monovision, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Therefore, caution should be exercised. During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision, and straight ahead and upward gaze that monovision contact lenses provide.

B. Eye Selection

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

1. **Ocular Preference Determination Methods**

   Method 1: Determine which eye is the "sighting 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 hand-held trial lens equal to the spectacle near ADD 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

Other methods include the "Refractive Error Method" and the "Visual Demands Method."

2. **Refractive Error Method**

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

3. **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 function best with the near lens on the left eye.

C. Special Fitting Characteristics

1. **Unilateral Vision Correction Requirement**

   There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens whereas a bilateral myope would require corrective lenses on both eyes.

   Example:

   A presbyopic emmetropic patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without correction.

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

2. **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.

3. **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 "General Fitting Guidelines" for base curve selection described in this guide.

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

   Allow the lenses to settle for about 20 minutes with the correct power lenses 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 tests 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.

4. **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.

5. **Other Suggestions**

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

   - Have a third contact lens (distance power) to use when critical distance viewing is needed.
   - Have 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 their state driver's license requirements with a monovision correction.
   - Make use of proper illumination when carrying out visual tasks.

   Monovision fitting success can be improved with 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 clear near vision and straight-ahead and upward gaze with monovision.

The decision to fit a patient with monovision correction is most appropriately left to the Eye Care Professional in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the PATIENT INSTRUCTION GUIDE for these lenses. Copies are available for download from www.acuvue.com.

PATIENT MANAGEMENT

- **Follow the accepted standard of care in fitting and following up with your patient.**
- **Schedule the appropriate follow-up examination.**
- **Preferably, at the follow-up visits, lenses should have been worn for at least six hours.**
- **Provide the patient with a copy of the PATIENT INSTRUCTION GUIDE for these lenses, which can be found at www.acuvue.com. REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE (DAILY DISPOSABLE).**

WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Professional. Regular checkups, as determined by the Eye Care Professional, are also extremely important.

Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum wearing schedule. Maximum wearing time should be determined by the Eye Care Professional based upon the patient's physiological eye condition, because individual response to contact lenses varies.

The maximum suggested wearing time for these lenses is:

Day	Hours
1	6-8
2	8-10
3	10-12
4	12-14
5 and after	all waking hours

REPLACEMENT SCHEDULE

These lenses are indicated for daily disposable wear and should be discarded upon removal.

LENS CARE DIRECTIONS

When lenses are dispensed, the Eye Care Professional should provide the patient with appropriate and adequate warnings and instructions for daily disposable lens wear.

The Eye Care Professional should review with patients that no cleaning or disinfection is needed with disposable lenses. Patients should always dispose of lenses when they are removed and have spare lenses or spectacles available.

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Eye Care Professionals may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Care for a Sticking (Non-Moving) Lens

During removal, if the lens sticks to the eye, the patient should be instructed to apply a few 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 after a few minutes, the patient should immediately consult the Eye Care Professional.

EMERGENCIES

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

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing these lenses or experienced with the lenses should be reported to:

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256
USA
Tel: 1-800-843-2020
www.acuvue.com

20401298

In Canada: Johnson & Johnson Vision Care division of Johnson & Johnson Inc.
In USA: Johnson & Johnson Vision Care, Inc.
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PACKAGE INSERT & FITTING INSTRUCTION GUIDE

1-DAY ACUVUE® OASYS MAX

ACUVUE® OASYS MAX 1-Day Contact Lenses
ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses

senofilcon A Soft (hydrophilic) Contact Lenses for Daily Disposable Wear

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

This Package Insert and Fitting Guide is intended for the Eye Care Professional, but should be made available to patients upon request.

The Eye Care Professional should provide the patient with the appropriate instructions that pertain to the patient's prescribed lenses. Copies are available for download at www.acuvue.com.

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

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	Caution, Consult Instructions for Use
	Date of Manufacture
	Manufacturer
	Use-By Date (expiration date)
LOT	Batch Code
STERILE	Sterilized Using Steam Heat
	Indicates a Single Sterile Barrier System
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
MULTIFOCAL	Multifocal Lenses
CE 2797	CE Mark and Identification number of Notified Body
UV BLOCKING	UV Blocking
	Fee Paid for Waste Management
Rx Only	CAUTION: US Federal law restricts this device to sale by or on the order of a licensed practitioner

SYMBOL	DEFINITION
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)
EC REP	Authorized Representative in the European Community
	Contains Hazardous Substances
	Do Not Re-Use (Single Use)
	Do Not Use if Package is Damaged
MD	Medical Device Symbol
A. B.	Package Opening Icon (Blister)
	Package Opening Icon (Carton)
L	"Low" near ADD
M	"Medium" near ADD
H	"High" near ADD
MAX ADD	Near ADD
LOW	"Low" near ADD
MID	"Medium" near ADD
HGH	"High" near ADD

Visit www.acuvue.com/guides for additional information about symbols.

DESCRIPTION

ACUVUE® OASYS MAX 1-Day Contact Lenses are soft (hydrophilic) contact lenses available as spherical lenses and multifocal lenses.

These lenses are made of a silicone hydrogel material (senofilcon A) containing an internal wetting agent and are tinted using Reactive Blue Dye #247 to make lenses more visible for handling.

A benzotriazole ultraviolet (UV) absorbing monomer is used to block UV radiation (280 nm – 380 nm) in combination with a novel fused tricyclic chromophore that also blocks UV radiation and partially filters high energy visible radiation (HEV)* in the range of 380 nm to 450 nm. The light transmittance characteristics for these lenses are less than 1% in the UVB range of 280 nm to 315 nm and 10% in the UVA range of 315 nm to 380 nm. The thinnest lenses transmit ≤ 45% of the radiation in the range from 380 nm to 450 nm. Please see HEV filtering NOTE in the ACTIONS section below.

Lens Properties:

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.42
- Visible Light Transmittance: ≥78%
- HEV Light Transmittance*: ≤ 45%
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability (Dk):

VALUE	METHOD
103 x 10^{-11} (cm^2/sec) (ml O_2/mL x mm Hg) @ 35°C	Fatt (boundary corrected, edge corrected)

Lens Parameter Ranges:

- Diameter (DIA): 12.0 mm to 15.0 mm
- Center Thickness: varies with power
- Base Curve (BC): 7.85 mm to 10.00 mm
- Spherical Power (D): -20.00D to +20.00D
- Multifocal ADD Power: +0.25D to +4.00D

Each lens is supplied in a foil-sealed plastic package containing borate buffered saline solution with methyl ether cellulose.

AVAILABLE LENS PARAMETERS

The ACUVUE® OASYS MAX 1-Day Contact Lenses (senofilcon A) are hemispherical shells of the following dimensions:

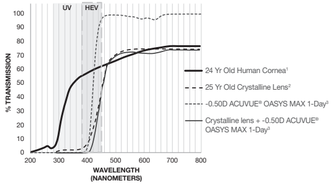
Diameter (DIA):	14.3 mm
Center Thickness:	0.085 mm to 0.221 mm (varies with power)
Base Curve (BC):	8.5 mm, 9.0 mm
Powers (D):	-12.00D to +8.00D

The ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses (senofilcon A) are hemispherical shells of the following dimensions:

Diameter (DIA):	14.3 mm
Center Thickness:	0.070 mm to 0.191 mm (varies with power)
Base Curve (BC):	8.4 mm
Powers (D):	-9.00D to +6.00D
ADD Powers (D):	+1.25D (LOW), +1.75D (MID), +2.50D (HGH)

TRANSMITTANCE CURVE

ACUVUE® OASYS MAX 1-Day Contact Lenses (senofilcon A) vs. 24 yr. old human cornea and 25 yr. old human crystalline lens.



[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. 19, figure 5
[3]The data was obtained from measurements taken through the central 6 mm portion for the thinnest single vision lens (-0.50D lens, 0.085mm center thickness).

ACTIONS

In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

These lenses contain UV and HEV* light absorbing monomers to help protect against transmission of harmful UV radiation to the cornea and into the eye and reduce transmittance of HEV* light. The light transmittance characteristics for these lenses are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 315 nm to 380 nm for the entire power range. The thinnest lenses transmit ≤ 45% of the radiation across the high energy visible* light wavelength in the range from 380 nm to 450 nm. The visible light transmittance in the range from 380 nm to 780 nm is greater than or equal to 78% depending on the lens thickness.

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

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

***NOTE: Filtering of HEV light by contact lenses has not been demonstrated to confer any health benefit to the user, including but not limited to retinal protection, protection from cataract progression, reduced eye strain, improved contrast, improved acuity, reduced glare, improved low light vision, or improved circadian rhythm/sleep cycle. The Eye Care Professional should be consulted for more information.**

INDICATIONS (USES)

ACUVUE® OASYS MAX 1-Day Contact Lenses (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have 1.00D or less of astigmatism that does not interfere with visual acuity.

ACUVUE® OASYS MAX 1-Day MULTIFOCAL Contact Lenses (senofilcon A) are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are presbyopic and may be nearsighted (myopic) or farsighted (hyperopic) and may have 0.75D or less of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for daily disposable wear. Therefore, no cleaning or disinfection is required. Lenses should be discarded upon removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE these lenses when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eye)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Ocular irritation due to allergic reactions which may be caused by use of contact lens solutions (i.e. rewetting drops) that contain chemicals or preservatives (such as mercury or Thimerosal, etc.) to which some people may develop an allergic response
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses
- Any active corneal infection (bacterial, fungal, protozoal, or viral)
- If eyes become red or irritated

WARNINGS

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

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. IF THE PATIENT EXPERIENCES:

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

THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PROFESSIONAL.

- Patients should be instructed not to wear their lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when lenses are worn overnight, and that the risk of ulcerative keratitis is greater for extended wear contact lens users than for daily wear users.[4]
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products are essential for the safe use of these products.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care.

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

Specific Instructions for Use and Warnings:

- **Water Activity**

Instruction for Use

Do not expose contact lenses to water while wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If lenses have been submersed in water when participating in water sports or swimming in pools, hot tubs, lakes, or oceans, the patient should be instructed to discard them and replace them with a new pair. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any activity involving water.

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen 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 Professional.
- Patients who wear these lenses to correct presbyopia using monovision or multifocal correction may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes unless otherwise indicated. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated.

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

Handling Precautions:

- Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- **DO NOT** use if the sterile blister package is opened or damaged.
- Always wash, rinse, and dry hands before handling lenses. It is best to put on lenses before putting on makeup.
- DO NOT touch contact lenses with fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the "Patient Instruction Guide" for these lenses and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container. Slide the lens up the side of the bowl until it is free of the container.

Lens Wearing Precautions:

- If the lens sticks (stops moving) on the eye, follow the recommended directions in "*Care for a Sticking (Non-Moving) Lens**. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- The patient should be advised to never allow anyone else to wear their lenses. Sharing lenses greatly increases the chance of eye infections.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the Eye Care Professional about wearing lenses during sporting activities.
- The patient should be advised to never rinse the lenses in water from the tap. Tap water contains many impurities that can contaminate or damage the lenses and may lead to eye infection or injury.

Lens Care Precautions:

- The patient should be informed that no cleaning or disinfection is needed when lenses are worn for daily disposable wear. Patients should always dispose of lenses when removed and have spare lenses or spectacles available.

Other Topics to Discuss with Patients:

- Always contact the Eye Care Professional before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- Do not change lens type (e.g. brand name, etc.) or parameters (e.g. diameter, base curve, lens power, etc.) without consulting the Eye Care Professional.
- Instruct patients to always confirm the lens parameters printed on the multi-pack and on the individual lens package match their prescription. If there is a mismatch the patient should not use the product.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Who Should Know That the Patient is Wearing Contact Lenses?

- Patients should inform all doctors (Health Care Professionals) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur when wearing contact lenses:

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

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

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

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS. If the problem or discomfort stops, the patient should discard the lens and place a new fresh lens on the eye.

If after inserting the new lens, the problem continues, the patient should be directed to IMMEDIATELY REMOVE THE LENS AND CONTACT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

GENERAL FITTING GUIDELINES

A. Patient Selection

Patients selected to wear these lenses should be chosen based on:

- Motivation to wear lenses
- Ability to follow instructions regarding lens wear and care
- General health
- Ability to adequately handle and care for the lenses
- Ability to understand the risk and benefits of lens wear

Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription (including determining the preferred reading distance for presbyopes), keratometry, and biomicroscopic evaluation.

Based on this evaluation, if it is determined that the patient is eligible to wear these lenses, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

C. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if necessary.

D. Base Curve Selection (Trial Lens Fitting)

The following trial lenses should be selected for patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

- ACUVUE® OASYS MAX 1-Day (senofilcon A): 8.5 mm/14.3 mm
- ACUVUE® OASYS MAX 1-Day (senofilcon A): 9.0 mm/14.3 mm
- ACUVUE® OASYS MAX 1-Day MULTIFOCAL (senofilcon A): 8.4 mm/14.3 mm

The trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

1. Criteria of a Properly Fit Lens

   A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink, and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released.

2. Criteria of a Flat Fitting Lens

   A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink, and/or edge standoff. If the lens is judged to be flat fitting, it should not be dispensed to the patient.