

ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) Visibility Tinted with UV Blocker for Daily and Extended Wear.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
	Diameter
	Base Curve
	Diopter (lens power)
	Quality System Certification Symbol
	UV-Blocking
	Fee Paid for Waste Management
	Peel Back Foil
	CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Center Thickness

	Lens Orientation Correct
	Lens Inside Out

Spherical Lenses For: Myopia, Hyperopia, Phakic or Aphakic

DESCRIPTION

The ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) Soft (hydrophilic) are available as spherical lenses. The lenses are made of a silicone hydrogel material containing an internal wetting agent with visibility tinted UV absorbing monomer. The ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) Contact Lens Visibility Tinted with UV Blocker are tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling. A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 nm to 380 nm for the entire power range.

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 – 1.12
- Refractive Index: 1.42
- Light Transmittance: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 38%
- Oxygen Permeability:

VALUE

103 x 10⁻¹¹ (cm²/sec)
(ml O₂/ml x mm Hg) at 35°C
122 x 10⁻¹¹ (cm²/sec)
(ml O₂/ml x mm Hg) at 35°C

METHOD

Fatt (boundary corrected, edge corrected)
Fatt (boundary corrected, non-edge corrected)

The ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) are a hemispherical or hemitoric shell of the following dimensions:

Diameter Range: 12.0mm to 15.0mm

Center Thickness:
Low minus lens – varies with power (e.g., -4.00D: 0.070mm)
Plus lens – varies with power (e.g., +4.00D: 0.170mm)

Base Curve Range:7.85mm to 10.00mm

Power Range:
Daily Wear -20.00D to +20.00D
Extended Wear -20.00D to +14.00D

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 Professional. It is recommended that contact lens wearers see their Eye Care Professional routinely as directed.

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.

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

• Patients who wear the ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) to correct presbyopia using Monovision 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. 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.

• 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.

• Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

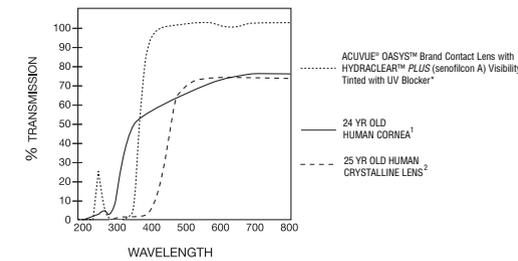
Eye Care Professionals should carefully instruct frequent replacement lens wear patients about the following care regimen and safety precautions:

AVAILABLE LENS PARAMETERS

Diameter:
14.0mm
Center Thickness:
Low minus lens – varies with power (e.g., -4.00D: 0.070mm)
Plus lens – varies with power (e.g., +4.00D: 0.170mm)
Base Curve:
8.4 mm
Power Range:
-12.00D to +8.00D

TRANSMITTANCE CURVES

ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) visibility tinted with UV blocker, 24 yr. old human cornea and 25 yr. old human crystalline lens



* The data was obtained from measurements taken through the central 3-5mm portion for the thinnest marketed lens (-1.00D lens, 0.070mm center thickness)

1. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
2. Waxler, M. Hitchens, 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 surrounding area. You should continue to use UV-absorbing eyewear as directed.

- 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.
- Always use fresh, unexpired lens care solutions and lenses.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A).
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions in "Care For A Dried Out (Dehydrated) Lens" if lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions in "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 Professional.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants 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 contact lenses with the 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, cleaning, disinfecting, storing and wearing instructions in the "Patient Instruction Guide" for the ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) and those prescribed by the Eye Care Professional.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.

ACTIONS

In its hydrated state, the ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A), when placed on the cornea, act as a refracting medium to focus light rays on the retina.

The transmittance characteristics are less than 1% in the UVB range of 280nm to 315nm and less than 10% in the UVA range of 316nm to 380nm for the entire power range.

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

INDICATIONS (USES)

The ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.

The ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care Professionals may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement (see "Wearing Schedule"). When prescribed for frequent/planned replacement wear, the lenses may be cleaned and disinfected using a chemical disinfection system only.

The ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) may be prescribed for daily and extended wear for up to 6 nights/7 days of continuous wear. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

- Ask the Eye Care Professional about wearing lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Inform the doctor (Health Care Professional) 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 and the packing solution into the hand.
- Do not touch the lens with fingernails.
- Always discard lenses worn on a disposable or frequent replacement schedule after the recommended wearing schedule prescribed by the Eye Care Professional.
- Always contact the Eye Care Professional 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.
- 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.
- 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 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 excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photo-phobia, 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?
- Do I continue to see well?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS.

If the discomfort or problem stops, the patient should then look closely at the lens.

If the lens is in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and apply a new fresh lens on the eye.

If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, he or she should be instructed to dispose of the lens and apply a new fresh lens.

If the problem continues, the patient SHOULD NOT put the lens back on the eye but IMMEDIATELY CONSULT 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.

FITTING

Conventional methods of fitting contact lenses apply to the ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A). For a detailed description of the fitting techniques, refer to the "ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) Fitting and Patient Management Guide", copies of which are available from:



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Vision Care, Inc.

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LENS CASE CLEANING AND MAINTENANCE (Frequent Replacement Lens Wearers Only)

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions 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 your Eye Care Professional.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If the frequent replacement lens is off the eye and exposed to air for 30 minutes to 1 hour or more, its surface will become dry and gradually become non-wetting. If this should occur, discard the lens and use a new one.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), 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.

IN OFFICE USE OF TRIAL LENSES

For fitting and diagnostic purposes, the lenses should be discarded after a single use and not be re-used from patient to patient.

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.

HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with 0.005% methyl ether cellulose. The plastic package is marked with base curve, diopter power, diameter, color (visibility tint), lot number and expiration date.

WEARING SCHEDULE

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

For Daily Wear, VISTAKON® recommends that the ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) prescribed for frequent replacement wear be discarded and replaced with a new lens every 2 weeks. However, the Eye Care Professional is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient. When prescribed for disposable wear, the ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS should be discarded upon removal.

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

EXTENDED WEAR

The Eye Care Professional 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.

ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) may be prescribed for daily and extended wear for up to 6 nights/ 7 days of continuous wear. Not all patients can achieve the maximum wear time. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Professional.

Once removed, it is recommended that the lens remain out of the eye for a period of rest overnight or longer and discarded in accordance with the prescribed wearing schedule. The Eye Care Professional should examine the patient during the early stages of extended wear.

LENS CARE DIRECTIONS

For ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) prescribed for disposable wear: The Eye Care Professionals 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 replacement lenses or spectacles available.

For ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) prescribed for frequent replacement wear: Eye Care Professionals should review with the patient, lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

GENERAL LENS CARE (To First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions

- Always wash, rinse and dry hands before handling contact lenses.
- Always use fresh, **unexpired** lens care solutions.
- Use the recommended system of lens care, chemical (not heat), and carefully follow instructions on solution labeling. Different solutions cannot always be used together and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- 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, and disinfect lenses according to the schedule prescribed by the Eye Care Professional. Enzyme as frequently as recommended by the Eye Care Professional. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Clinical studies were conducted with ReNu® Multi-Plus cleaning and disinfection system.
- Since the lens material contains silicone, the wettability may differ when different lens care products are used. The Eye Care Professional should recommend a care system that is appropriate for the ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A). 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 instructions.
- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A) or experienced with the lenses should be reported to:



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cleaning solution, mucus and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Repeat the procedure for the second lens.

- After cleaning, **disinfect** lenses using the system recommended by the manufacturer and/or the Eye Care Professional.
- 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 Professional for information on 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 case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your Eye Care Professional.
- Eye Care Professionals may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn.

CHEMICAL (NOT HEAT) DISINFECTION OF LENSES WORN ON A FREQUENT REPLACEMENT SCHEDULE

- **Clean** the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **After cleaning**, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the Eye Care Professional.
- 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 applying 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 on the eye should reduce the potential for irritation.

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

This Package Insert 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 patient instructions that pertain to the patient's prescribed lens.

ACUVUE® OASYS™ Brand Contact Lenses with HYDRACLEAR™ PLUS (senofilcon A)

Visibility Tinted with UV Blocker
For Daily and Extended Wear



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Printed in U.S.A.

Revision date 01/06

Revision number: AO-01-06-05b