

- lens solutions.
- ◆ Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the VISTAKON® (etafilcon A) contact lenses.
- ◆ 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 (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.
- 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, which causes distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the specific "Patient Instruction Guide" pertaining to the VISTAKON® (etafilcon A) contact lens and its prescribed wearing schedule.
- Never wear lenses beyond the period recommended by the Eye Care Professional.
- Never allow anyone else to wear your lenses. They have been prescribed to fit your eyes and to correct your vision to the degree necessary. Sharing lenses greatly increase the chances 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.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your Eye Care Professional about wearing contact 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 your 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 VISTAKON® (etafilcon A) Contact 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.

LENS CARE DIRECTIONS

For etafilcon A contact lenses prescribed for daily disposable wear: The Eye Care Professional should review with the patient 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 etafilcon A contact lenses prescribed for frequent replacement wear: The Eye Care Professional should review with the patient the 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)

Frequent replacement 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.
- The Eye Care Professional should recommend a care system that is appropriate for the VISTAKON® (etafilcon A) contact lenses prescribed on a frequent replacement schedule. Each lens care product contains specific directions for use and important safety information, which should be read carefully and 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 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, disinfect lenses using the system recommended by the manufac-

- 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 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,ritis 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?
 - ◆ 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 insert 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 insert a new fresh lens.

LENS CASE CLEANING AND MAINTENANCE

(For etafilcon A contact lenses prescribed for Frequent Replacement Lens Wear Only)

Contact lens cases can be a source of bacterial 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 from 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.

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

ACUVUE® Brand, ACUVUE®2 Brand, ACUVUE® Brand BIFOCAL, and SUREVUE® Contact Lenses:

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. The plastic package is marked with base curve, diopter power, diameter, lot number and expiration date.

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 VISTAKON® (etafilcon A) Contact Lenses. For a detailed description of the fitting techniques, refer to:

Product ACUVUE® and ACUVUE® 2 Lenses	"ACUVUE® Brand and ACUVUE® 2 Brand Contact Lenses Fitting and Patient Management Guide"
ACUVUE® 2 <i>COLOURS</i> ™ Lens	"ACUVUE® 2 <i>COLOURS</i> ™ Brand Contact Lenses Fitting and Patient Management Guide"
<i>1•DAY</i> ACUVUE® and <i>1•DAY</i> ACUVUE® MOIST™ ACUVUE® <i>BIFOCAL</i>	" <i>1•DAY</i> ACUVUE® Brand Contact Lens Fitting and Patient Management Guide" "ACUVUE® Brand <i>BIFOCAL</i> Contact Lens Fitting and Patient Management Guide"
ACUVUE® <i>TORIC</i> Lens	"ACUVUE® Brand <i>TORIC</i> Contact Lens Fitting and Patient Management Guide"
SUREVUE® Lenses	"SUREVUE® Contact Lens Fitting and Patient Management Guide"
Copies are available from: VISTAKON® , Division of Johnson & Johnson Vision Care, Inc. PO Box 10157 Jacksonville, FL 32247-0157 1-800-843-2020	

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.

ACUVUE®, ACUVUE®2, ACUVUE®2 *COLOURS*™, ACUVUE® *BIFOCAL* and ACUVUE® TORIC Lenses are indicated for daily wear (less than 24 hours, while awake) and for extended wear (greater than 24 hours, including while asleep).

SUREVUE® Lenses are indicated for daily wear (less than 24 hours, while awake). *1•DAY* ACUVUE® and *1•DAY* ACUVUE® MOIST™ lenses are intended to be worn once on a daily disposable basis (less than 24 hours, while awake) and should be discard-

ACUVUE® Brand *TORIC* Contact Lenses:

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. The plastic package is marked with base curve, diopter power, axis, diameter, cylinder, lot number and expiration date.

1•DAY ACUVUE® Brand Contact Lenses:

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. The plastic package is marked with base curve, diopter power, diameter, lot number and expiration date.

1•DAY ACUVUE® MOIST™ Brand Contact Lenses

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution with Povidone. The plastic package is marked with base curve, diopter power, diameter, lot number and expiration date.

ACUVUE® 2 *COLOURS*™ Contact Lenses:

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. The plastic package is marked with base curve, diopter power, diameter, lens color, lot number and expiration date.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing ACUVUE® Brand, ACUVUE®2 Brand, ACUVUE®2 *COLOURS*™ Brand, ACUVUE® Brand *BIFOCAL*, ACUVUE® Brand TORIC, *1•DAY* ACUVUE® Brand, *1•DAY* ACUVUE® MOIST™ Brand, and SUREVUE® Contact Lenses or experienced with the lenses should be reported to:



VISTAKON® , Division of Johnson & Johnson Vision Care, Inc.
P. O. Box 10157
Jacksonville, FL 32247-0157
Tel 1-800-843-2020 • Fax 1-904-443-1826



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ed upon removal.

VISTAKON® (etafilcon A) Contact Lenses when worn on a daily basis and replaced at intervals ranging from 1 day to 2 weeks, or when worn on a daily disposable basis, and disposed of after a single daily use, may reduce the risk of developing giant papillary conjunctivitis, when compared to lenses replaced at intervals greater than 2 weeks.

VISTAKON® recommends that etafilcon A contact lenses 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.

Studies have not been completed to show that *1•DAY* ACUVUE®, *1•DAY* ACUVUE® MOIST™, and SUREVUE® Lenses are safe to wear during sleep.

DAILY WEAR

The maximum daily wearing time should be determined by the Eye Care Professional based upon the patient's individual response to contact lenses. The Eye Care Professional should emphasize the importance of adhering to the initial maximum daily wearing time. 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 VISTAKON® (etafilcon A) Contact Lens indicated for extended wear is recommended for 1-7 days/6 nights of continuous wear. Once the lens is removed, it is recommended that the patient's eyes should have a rest period of overnight or longer. The Eye Care Professional should determine the wearing time of soft (hydrophilic) contact lenses used for extended wear.

It is recommended that the new contact lens wearer first be evaluated on a daily wear schedule. If, in the opinion of the Eye Care Professional, the patient is determined to be an acceptable extended wear candidate, the Eye Care Professional is encouraged to determine a wearing schedule based upon the response of the patient.

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® Brand Contact Lens

ACUVUE® 2 Brand Contact Lens

ACUVUE® Brand *BIFOCAL* Contact Lens

ACUVUE® Brand *TORIC* Contact Lens

(etafilcon A)

VISIBILITY TINTED WITH UV BLOCKER
For Daily and Extended Wear

1•DAY ACUVUE® Brand Contact Lens

(etafilcon A)

CLEAR and VISIBILITY TINTED WITH UV BLOCKER
For Daily Wear

1•DAY ACUVUE® MOIST™ Brand Contact Lens

(etafilcon A)

VISIBILITY TINTED WITH UV BLOCKER
For Daily Wear

ACUVUE® 2 *COLOURS*™ Brand Contact Lens

(etafilcon A)

With UV BLOCKER
For Daily and Extended Wear

SUREVUE® Contact Lens

(etafilcon A)

VISIBILITY TINTED WITH UV BLOCKER
For Daily Wear



