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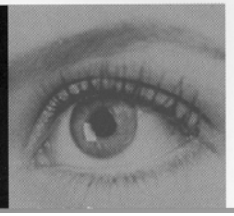

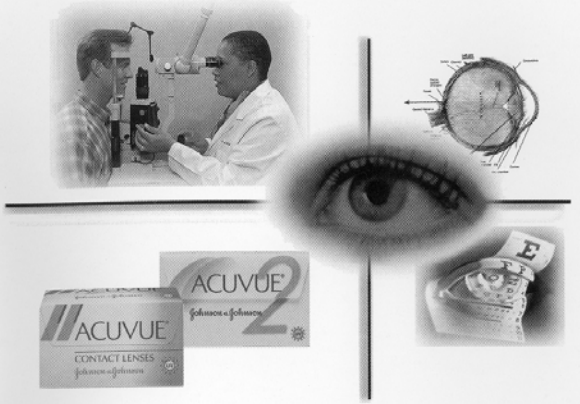

ACUVUE® & ACUVUE® 2

VISTAKON
Johnson & Johnson VISION PRODUCTS, INC.

ACUVUE® & ACUVUE® 2
(etafilcon A)
CONTACT LENS

FITTING AND PATIENT MANAGEMENT GUIDE

For ACUVUE & ACUVUE 2 (etafilcon A) Contact Lenses
Visibility Tint With UV Blocker

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ACUVUE® & ACUVUE®2

INTRODUCTION AND PRODUCT DESCRIPTION

ACUVUE® and ACUVUE® 2 (etafilcon A) Soft (hydrophilic) Contact Lenses are made from etafilcon A with a water content of 58% by weight.

For a complete listing of available lens parameters, please refer to "CURRENTLY AVAILABLE LENS PARAMETERS".

See Package Insert for "Actions", "Contraindications", "Warnings", "Precautions", "Adverse Reactions" and "Patient Lens Care Directions".

CAUTION: Federal, U.S.A. Law Prohibits Dispensing Without a Prescription.

Product Description

The ACUVUE® and ACUVUE® 2 (etafilcon A) Soft (hydrophilic) Contact Lenses are available as a spherical lens. The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1,1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate. The ACUVUE and ACUVUE 2 Contact Lenses with Visibility Tint are tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling. In the ACUVUE and ACUVUE 2 Contact Lenses with Visibility Tint and UV Blocker, a benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280 nm to 315 nm and less than 30% in the UVA range of 316 nm to 380 nm.

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.

CURRENTLY AVAILABLE LENS PARAMETERS

Currently Available Lens Parameters (ACUVUE)

Minus

Base Curve	Diameter	Power Range
8.4mm, 8.8mm	14.0mm	-0.50D to -6.00D (in 0.25D increments)
9.3mm	14.4mm	-6.50D to -9.00D (in 0.50D increments)
8.8mm	14.0mm	-9.50D to -11.00D (in 0.50D increments)

Plus

9.1mm	14.4mm	+0.50D to +6.00D (in 0.25D increments) +6.50D to +8.00D (in 0.50D increments)

Currently Available Lens Parameters (ACUVUE 2)

Minus

Base Curve	Diameter	Power Range
8.3mm, 8.7mm	14.0mm	-0.50D to -6.00D (in 0.25D increments) -6.50D to -12.00D (in 0.50D increments)

Plus

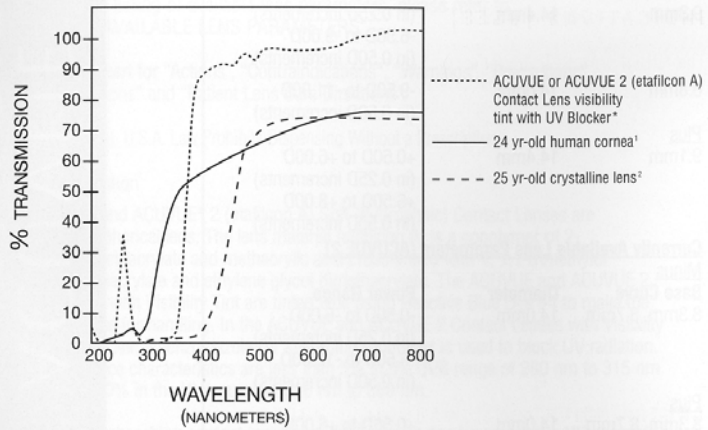
8.3mm, 8.7mm	14.0mm	+0.50D to +6.00D (in 0.25D increments) +6.50D to +8.00D (in 0.50D increments)

Center Thickness: for ACUVUE and ACUVUE 2

low minus lens–varies with power (e.g., -3.00D: 0.070mm ACUVUE)
(e.g., -3.00D: 0.084mm ACUVUE 2)
plus lens–varies with power (e.g., +3.00D: 0.170mm ACUVUE and ACUVUE 2)

TRANSMITTANCE CURVES

ACUVUE or ACUVUE 2 (etafilcon A) Contact Lens visibility tint 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 (-2.50D ACUVUE lens, 0.07mm center thickness).

1. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21

2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 10, figure 5

WEARING RESTRICTIONS AND INDICATIONS

ACUVUE® & ACUVUE® 2

ACTIONS

See package insert for "Actions".

INDICATIONS (USES)

The ACUVUE and ACUVUE 2 Contact Lenses (spherical) are indicated for daily and extended wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

ACUVUE and ACUVUE 2 UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The lens may be prescribed for either daily wear or for extended wear from 1-7 days between removals for cleaning and disinfection or disposal, as recommended by the Eye Care Practitioner. Eye Care Practioners may prescribe the lens 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 lens may be disinfected using a chemical disinfection system only.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS

See package insert for "Contraindications", "Warnings", "Precautions" and "Adverse Reactions".

Patient Selection

You should first assess the patient's needs and ensure that the patient is an appropriate candidate for the ACUVUE® or ACUVUE 2 (etafilcon A) Contact Lens. The ACUVUE and ACUVUE 2 Contact Lenses, like other soft contact lenses, will require the appropriate and usual physiological and diagnostic assessments necessary to ensure proper patient selection. Refer to the package insert for additional information on patient selection.

1.Presbyopic Needs Assessment (Monovision)

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 1.00D) in one eye may not be a good candidate for presbyopic correction with Monovision with the ACUVUE or ACUVUE 2 (etafilcon A) Contact Lens.

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

(a) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(b) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with Monovision correction should be advised to not drive with this correction, OR may require that additional overcorrection be prescribed.

2. Patient Education (Monovision)

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 alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

3. Pre-fitting Examination (Monovision)

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

- determine whether a patient is a suitable candidate for daily and extended wear contact lenses (consider patient hygiene and mental and physical state),
- make ocular measurements for the initial contact lens parameter selection, and
- collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include a determination of optimal distance and near spectacle correction and corneal curvature measurements. The near correction should be determined at the midpoint of the patient's habitual reading distance. When more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers. Prescribe the least plus (most minus) of the powers that meet the patient's near requirements.

LENS SELECTION

Spherical
A. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to select the ACUVUE or ACUVUE 2 trial lens power. Remember to compensate for vertex distance if the refraction is greater than ±4.00D.

B. Base Curve Selection (Trial Lens Fitting)
ACUVUE
Minus Power Lenses

The ACUVUE 8.8mm/14.0mm trial lens should be the initial lens of choice for all myopic patients regardless of keratometry readings. In clinical tests ACUVUE 8.8mm/14.0mm Contact Lenses have performed successfully on eyes with a range of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

An ACUVUE 8.8mm/14.0mm trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses. A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement with the blink to provide tear exchange under the contact lens 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. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

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 edge standoff. If the ACUVUE 8.8mm/14.0mm Contact Lens is judged to be flat fitting, the ACUVUE 8.4mm/14.0mm Contact Lens should be trial fit and evaluated after sufficient adjustment time. Once again, a properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement, with the blink, to provide tear exchange under the contact lens 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. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

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 ACUVUE 8.8mm/14.0mm Contact Lens is judged to be steep fitting, the ACUVUE 9.3mm/14.4mm Contact Lens should be trial fit and evaluated after sufficient adjustment time. Once again, a properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement, with the blink, to provide tear exchange under the contact lens 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. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

ACUVUE 2
Minus Power Lenses

The ACUVUE 2, 8.7mm/14.0mm trial lens should be the initial lens of choice for all myopic patients regardless of keratometry readings. In clinical tests ACUVUE 2, 8.7mm/14.0mm Contact Lenses have performed successfully on eyes with a range of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

An ACUVUE 2, 8.7mm/14.0mm trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses. A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement with the blink to provide tear exchange under the contact lens 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. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

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 edge standoff. If the ACUVUE 2, 8.7mm/14.0mm Contact Lens is judged to be flat fitting,

the ACUVUE 2, 8.3mm/14.0mm Contact Lens should be trial fit and evaluated after sufficient adjustment time. Once again, a properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement with the blink to provide tear exchange under the contact lens 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. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

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 ACUVUE 2, 8.3mm/14.0mm Contact Lens is judged to be steep fitting, the ACUVUE 2, 8.7mm/14.0mm Contact Lens should be trial fit and evaluated after sufficient adjustment time. Once again, a properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement with the blink to provide tear exchange under the contact lens 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. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

ACUVUE
Plus Power Lenses

The ACUVUE 9.1mm/14.4mm Contact Lens should be selected for hyperopic patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status. An ACUVUE 9.1mm/14.4mm trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses. A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement with the blink to provide tear exchange under the contact lens 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. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

ACUVUE 2
Plus Power Lenses

The ACUVUE 2, 8.3mm or 8.7mm/ 14.0mm Contact Lens should be selected for hyperopic patients regardless of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status. An ACUVUE 2, 8.3mm or 8.7mm/ 14.0mm trial lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses. A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement with the blink to provide tear exchange under the contact lens 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. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

C. Final Lens Power

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

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 diopter) in one eye may not be a good candidate for Monovision correction with the ACUVUE or ACUVUE 2 (etafilcon A) Contact Lens.

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

(1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(2) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with Monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

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

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 an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

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

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.

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 when a bilateral myope may require only a distance lens.

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 a lens.

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.

Near ADD Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the mid-point 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.

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 the 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.

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 performances 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.

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 state licensing requirements with a Monovision correction.
- Make use of proper illumination when carrying out visual tasks.

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

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

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

All patients should be supplied with a copy of the "ACUVUE and ACUVUE 2 (etafilcon A) Patient Instruction Guide".

Dispensing Visit

Each sterile lens is supplied in a foil-sealed plastic package containing buffered saline solution. In removing the lens from the container, peel back the foil seal, place a finger on the lens and slide the lens up the side of the bowl of the lens package until it is free of the container.

- Evaluate the physical fit and visual acuity of the lens on each eye.
- Teach the patient how to insert and remove his or her lenses.
- Explain the daily and extended wear regimens and schedule a follow-up examination.
- PROVIDE THE PATIENT WITH A COPY OF THE APPROPRIATE ACUVUE AND ACUVUE 2 PATIENT INSTRUCTIONS (DISPOSABLE OR FREQUENT REPLACEMENT). REVIEW THESE INSTRUCTIONS WITH THE PATIENT SO THAT HE OR SHE CLEARLY UNDERSTANDS THE PRESCRIBED WEARING AND REPLACEMENT SCHEDULE.
- Recommend an appropriate cleaning and disinfecting system and provide the patient with instructions regarding proper lens care (see package insert). Chemical and hydrogen peroxide disinfection is recommended. Heat disinfection is not advised.
- Review the Package Insert for the ACUVUE and ACUVUE 2 (etafilcon A) Contact Lens and provide the patient with all of the relevant information and precautions on the proper use of the ACUVUE or ACUVUE 2 Contact Lens.
- 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 Practitioner, the patient is determined to be an acceptable daily and extended wear candidate, the Eye Care Practitioner is encouraged to determine a wearing schedule based upon the response of the patient.

Follow-Up Examinations

Follow-up care (necessary to ensure continued successful contact lens wear) should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wear schedule, lens replacement schedule, and proper lens care and handling procedures.

Recommended Follow-up Examination Schedule for ACUVUE or ACUVUE 2 Contact Lenses for Daily and Extended Wear

(complications and specific problems should be managed on an individual patient basis):

1. One week from the initial lens dispensing to patient
2. One month post-dispensing
3. Every three to six months thereafter

NOTE:Preferably, at the follow-up visits, lenses should be worn for at least six hours.

Recommended Procedures for Follow-up visits:

1. Solicit and record patient's symptoms, if any.
2. Measure visual acuity monocularly and binocularly at distance and near with the contact lenses.
3. Perform an over-refraction at distance and near to check for residual refractive error.
4. With the biomicroscope, judge the lens fitting characteristics (as described in the "General Fitting Guidelines") and evaluate the lens surface for deposits and damage.
5. Following lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein.
   - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
   - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, and 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.
6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

If any observations are abnormal, use professional judgement to alleviate the problem and restore the eye to optimal conditions. If the criteria for successful fit are not satisfied during any follow-up examinations, repeat the patient's trial fitting procedure and refit the patient.

Recommended Wearing Schedule

See package insert.

Patient Lens Care Directions

See package insert for "Lens Care Directions" for lenses worn on a frequent replacement schedule.

Chemical (not heat) Disinfection

See package insert for "Chemical Lens Disinfection" of lenses worn on a frequent replacement schedule.

Care For A Dried Out (dehydrated) Lens

See package insert for "Care For A Dehydrated Lens" when lenses are worn on a frequent replacement schedule.

Care For A Sticking (non-moving) Lens

See package insert for "Care For A Sticking Lens".

Reporting of Adverse Reactions

All serious adverse experiences and adverse reactions observed in patients wearing ACUVUE or ACUVUE 2 Contact Lenses or experienced with the lenses should be reported to:

VISTAKON
Johnson & Johnson VISION PRODUCTS, INC.

Vistakon, Johnson & Johnson Vision Products, Inc.
P.O. Box 10157
Jacksonville, FL 32247-0157
1-800-843-2020
www.acuvue.com

How Supplied

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

ACUVUE® & ACUVUE®2

ACUVUE® and ACUVUE® 2 (etafilcon A) CONTACT LENS
Visibility Tint with UV blocker

VISTAKON
Johnson & Johnson VISION PRODUCTS, INC.

IMPORTANT - Please read carefully and keep this information for future use. This package insert is intended for the Eye Care Practitioner, but should be made available to patients upon request. The Eye Care Practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

ACUVUE and ACUVUE 2 (etafilcon A) Soft (Hydrophilic) Contact Lenses Visibility Tint with UV blocker

SYMBOLS KEY
The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
LOT	Batch Code
STERILE	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
CE 0086	Quality System Certification Symbol
	UV Blocking
	Peel Back Foil
	Lens Orientation Correct (ACUVUE)
	Lens Inside Out (ACUVUE)
	Lens Orientation Correct (ACUVUE 2)
	Lens Inside Out (ACUVUE 2)

CAUTION: Federal U.S.A. Law Prohibits Dispensing Without A Prescription.

Spherical Lenses for:
Myopia
Hyperopia
Aphakic or Non-aphakic

DESCRIPTION
The ACUVUE and ACUVUE 2 (etafilcon A) Soft (hydrophilic) Contact Lenses are available as a spherical lens. The lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1, 1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate. The ACUVUE and ACUVUE 2 Contact Lens with Visibility Tint are tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling. In the ACUVUE and ACUVUE 2 Contact Lenses with Visibility Tint and UV Blocker, a benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280 nm to 315 nm and less than 30% in the UVA range of 316 nm to 380 nm. The ACUVUE and ACUVUE 2 Contact Lenses are a hemispherical shell of the following dimensions:

- Diameter: 12.0mm to 15.0mm
- Center Thickness:
  low minus lens - varies with power
  (e.g., -3.00D: 0.070mm) ACUVUE
  (e.g., -3.00D: 0.084mm) ACUVUE 2
  plus lens - varies with power
  (e.g., +3.00D: 0.170mm) ACUVUE and ACUVUE 2
- Base Curve: 7.85mm to 10.00mm
- Powers:
  Daily Wear -20.00D to +20.00D
  Extended Wear -20.00D to +14.00D

The physical/optical properties of the lens are:
- Specific Gravity (calculated): 0.98 - 1.12
- Refractive Index: 1.40
- Light Transmittance: 85% minimum
- Surface Character: Hydrophilic
- Water Content: 58%
- Oxygen Permeability:

VALUE	METHOD
28.0 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) at 35°C	Fatt (boundary corrected, non-edge corrected)
21.4 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) at 35°C	Fatt (boundary corrected, edge corrected)

CURRENTLY AVAILABLE LENS PARAMETERS (ACUVUE)

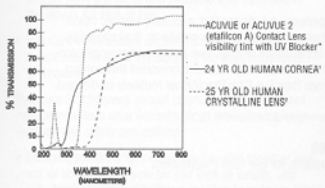
Base Curve	Diameter	Power Range
Minus		
8.4mm, 8.8mm	14.0mm	-0.50D to -6.00D (in 0.25D increments)
9.3mm	14.4mm	-6.50D to -9.00D (in 0.50D increments)
8.8mm	14.0mm	-9.50D to -11.00D (in 0.50D increments)
Plus		
9.1mm	14.4mm	+0.50D to +6.00D (in 0.25D increments) +6.50D to +8.00D (in 0.50D increments)

CURRENTLY AVAILABLE LENS PARAMETERS (ACUVUE 2)

Base Curve	Diameter	Power Range
Minus		
8.3mm, 8.7mm	14.0mm	-0.50D to -6.00D (in 0.25D increments) -6.50D to -12.00D (in 0.50D increments)
Plus		
8.3mm, 8.7mm	14.0mm	+0.50D to +6.00D (in 0.25D increments) +6.50D to +8.00D (in 0.50D increments)

Transmittance Curves

ACUVUE or ACUVUE 2 (etafilcon A) Contact Lens visibility tint 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 (-2.50D ACUVUE lens, 0.07mm center thickness).
1. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, figure 2-21
2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.10, figure 5

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

ACTIONS
In its hydrated state, the ACUVUE or ACUVUE 2 Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The average UV blocking of ACUVUE and ACUVUE 2 Contact Lenses with UV Blocker for UVA is 82% and for UVB is 97%.

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 Practitioner for more information.

INDICATIONS (USES)
The ACUVUE and ACUVUE 2 Contact Lenses (spherical) are indicated for daily and extended wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

ACUVUE and ACUVUE 2 UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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The lens may be prescribed for either daily wear or for extended wear from 1-7 days between removals for cleaning and disinfection or disposal, as recommended by the Eye Care Practitioner. Eye Care Practitioners may prescribe the lens 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 disinfected using a chemical disinfection system only.

CONTRAINDICATIONS (REASONS NOT TO USE)
DO NOT USE the ACUVUE or ACUVUE 2 Contact Lens 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 eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if non-aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the ACUVUE or ACUVUE 2 Contact Lens
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS
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, including lens cases, are essential for the safe use of these products. 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. The results of a study[1] indicate the following:

- The overall annual incidence of ulcerative keratitis in daily wear contact lens users is estimated to be about 4.1 per 10,000 persons and about 20.9 per 10,000 persons in extended wear contact lens users.
- The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact lens users than for daily wear users. When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily basis are excluded from the comparison, the risk among extended wear users is 10 to 15 times greater than among daily wear users.
- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is 9 times greater than among those who do not wear them overnight.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- The risk of ulcerative keratitis among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.

If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Practitioner. It is recommended that contact lens wearers see their Eye Care Practitioner routinely as directed.

1 New England Journal of Medicine, September 21, 1989

PRECAUTIONS
Special Precautions for Eye Care Practitioners

- 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 Practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Practitioner.

- Patients who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- 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 Practitioner'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 Practitioners should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

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

- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- 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 or ACUVUE 2 Contact Lens.
- 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 Practitioner.
- 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 and ACUVUE 2 Contact Lens and those prescribed by the Eye Care Practitioner.

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- Never wear lenses beyond the period recommended by the Eye Care Practitioner.
- 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 the Eye Care Practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into 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 Practitioner.
- Always contact the Eye Care Practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- 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 and 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?
– 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 fresh new lens.

If the problem continues, the patient SHOULD NOT put the lens back on the eye but IMMEDIATELY CONSULT HIS OR HER EYE CARE PRACTITIONER.

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 and ACUVUE 2 (etafilcon A) Contact Lenses. For a detailed description of the fitting techniques, refer to the "ACUVUE and ACUVUE 2 Contact Lens Fitting and Patient Management Guide", copies of which are available from:

VISTAKON™
Johnson & Johnson VISION PRODUCTS, INC.

Vistakon, Johnson & Johnson Vision Products, Inc.
P.O. Box 10157
Jacksonville, FL 32247-0157
1-800-843-2020

WEARING SCHEDULE

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

Vistakon recommends that the frequent replacement lens be discarded and replaced with a new lens every 2 weeks. However, the Eye Care Practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient. The disposable lens should be discarded upon removal.

The ACUVUE and ACUVUE 2 Contact Lenses are indicated for daily wear (less than 24 hours while awake) and for extended wear (greater than 24 hours, including while asleep).

DAILY WEAR

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 ACUVUE or ACUVUE 2 (etafilcon A) Contact Lens for Extended Wear is recommended for 1 to 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 wearing time of soft (hydrophilic) contact lenses used for extended wear should be determined by the Eye Care Practitioner.

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 Practitioner, the patient is determined to be an acceptable extended wear candidate, the Eye Care Practitioner is encouraged to determine a wearing schedule based upon the response of the patient.

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LENS CARE DIRECTIONS
DISPOSABLE LENS WEARERS: Eye Care Practitioners 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.

FREQUENT REPLACEMENT LENS WEARERS: Eye Care Practitioners 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 Practitioner. Enzyme as frequently as recommended by the Eye Care Practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- The Eye Care Practitioner should recommend a care system that is appropriate for the ACUVUE or ACUVUE 2 Contact Lens. 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 mixups), 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. Repeat the procedure for the second lens.
- After cleaning, **disinfect** lenses using the system recommended by the manufacturer and/or the Eye Care Practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the Eye Care Practitioner for information on 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 Practitioner.
- Eye Care Practitioners may recommend a **lubricating/rewetting** solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

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 Practitioner.
- When using hydrogen peroxide lens care systems, lenses **must be neutralized before wearing.** Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat the disinfection solution and lenses.**
- Leave the lenses in the unopened storage case until ready to put on the eyes.

Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

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 Practitioner.

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 Practitioner.

EMERGENCIES
The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER 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. The plastic package is marked with base curve, diopter power, diameter, color (visibility tint), lot number and expiration date.

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REPORTING OF ADVERSE REACTIONS
All serious adverse experiences and adverse reactions observed in patients wearing ACUVUE or ACUVUE 2 Contact Lenses or experienced with the lenses should be reported to:

VISTAKON
Johnson & Johnson VISION PRODUCTS, INC.

Vistakon, Johnson & Johnson Vision Products, Inc.
P.O. Box 10157
Jacksonville, FL 32247-0157
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NOTES