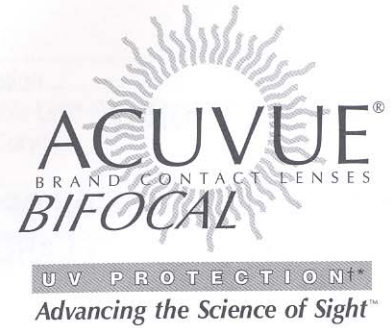


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Revision number: MF-04-01-00

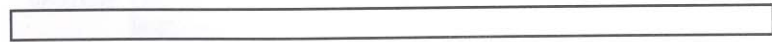
VISTAKON[®], Division of Johnson & Johnson Vision Care, Inc.
P.O. Box 10157
Jacksonville, Florida 32247-0157
1-800-843-2020
www.acuvue.com

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Johnson & Johnson Vision Care, Inc.



FITTING & PATIENT MANAGEMENT GUIDE

For ACUVUE[®] Brand *BIFOCAL* (etafilcon A) Contact Lenses
Visibility Tinted With UV Blocker



PRESCRIBING QUESTIONS?

**CALL THE VISTAKON® , DIVISION OF
JOHNSON & JOHNSON VISION CARE, INC.
PROFESSIONAL AFFAIRS
CONSULTATION TEAM:**

**1-877-334-EYES
(3937)**

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

* **WARNING:** UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed. **NOTE:** Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

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

INTRODUCTION & PRODUCT DESCRIPTION

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

ACUVUE® Brand *BIFOCAL* (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".

Product Description

The ACUVUE® Brand *BIFOCAL* (etafilcon A) Soft (hydrophilic) Contact Lens is available as a spherical bifocal 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® *BIFOCAL* Contact Lens with Visibility Tint is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling. A benzotriazole UV absorbing monomer is used to block

UV radiation. The UV Blocking averages 98% in the UVB range of 280 nm to 315 nm and 86% 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

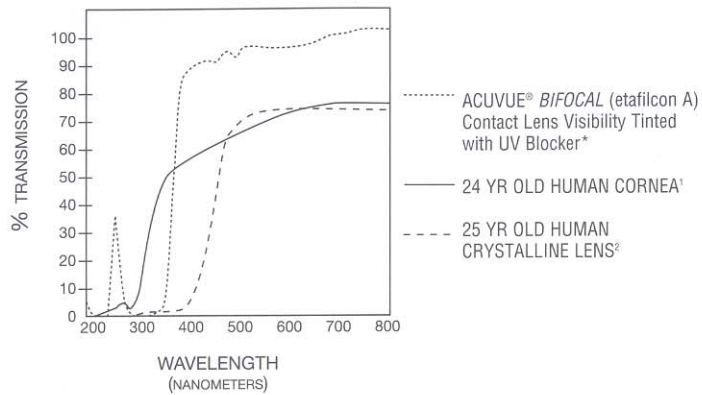
Base Curve	Diameter	Power Range
8.5mm	14.2mm	+6.00D to -9.00D (in 0.25D increments) Labeled Power = Measured Distance Power +0.25D
ADD Powers		+1.00D to +2.50D (in 0.50D increments) Labeled Power = Measured ADD Power -0.50D

Center Thickness

low minus lens - varies with power (e.g., -3.00D: 0.075mm)
plus lens - varies with power (e.g., +3.00D: 0.165mm)

TRANSMITTANCE CURVES & ACTIONS

ACUVUE® Brand *BIFOCAL* (etafilcon A) Contact Lens 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 (-3.00D ACUVUE® *BIFOCAL* Contact Lens, 0.075mm 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

ACTIONS

See Package Insert for "Actions".

WEARING RESTRICTIONS AND INDICATIONS

INDICATIONS (USES)

The ACUVUE® Brand *BIFOCAL* Contact Lens is indicated for daily wear or extended wear for the correction of distance and near vision in presbyopic aphakic or not-aphakic persons with non-diseased eyes who may have 0.75D or less of astigmatism.

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

The ACUVUE® *BIFOCAL* Contact 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 lens may be disinfected using a chemical disinfection (including hydrogen peroxide) system only.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS

See Package Insert for "Contraindications", "Warnings", "Precautions" and "Adverse Reactions".

GENERAL FITTING GUIDELINES

Patient Selection

You should first assess the patient's needs and motivation to ensure that the patient is an appropriate candidate for the ACUVUE® Brand *BIFOCAL* (etafilcon A) Contact Lens. The ACUVUE® *BIFOCAL* Contact Lens, 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

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 0.75D) in one or both eyes, may not be a good candidate for presbyopic correction with the ACUVUE® *BIFOCAL* 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 the ACUVUE® *BIFOCAL* Contact Lens. ACUVUE® *BIFOCAL* Contact Lens wear may not be optimal 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 the ACUVUE® *BIFOCAL* Contact Lens should be advised not to drive with this correction, OR may require that additional over-correction be prescribed.

2. Patient Education

All patients do not function equally well with presbyopic correction. Patients may not perform as well for certain tasks with this correction as they have with spectacles that correct for presbyopia. Each patient should understand that bifocal contact lenses, as well as other presbyopic alternatives, can create a vision compromise that may reduce visual acuity and depth perception for

GENERAL FITTING GUIDELINES

distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages of bifocal contact lenses as well as the advantages of clear near vision in straight-ahead and upward gaze that bifocal contact lenses provide.

3. Pre-fitting Examination

A pre-fitting patient history and examination are necessary to determine whether a patient is a suitable candidate for daily wear or extended wear contact lenses. Areas to be evaluated should include: patient hygiene, the patient's mental and physical state, motivation to wear contact lenses, and visual demands.

Clinical information should be collected and utilized to determine the initial ACUVUE® *BIFOCAL* Contact Lens parameters, and to establish a baseline to which post-fitting examination results can be compared. The pre-fitting clinical examination should include: a determination of optimal distance and near spectacle correction, corneal curvature measurements, and the status of ocular physiology. The near correction should be determined at the patient's

preferred reading distance.

Lens Parameter Selection (Trial lens fitting)

A trial fitting is performed in the office to allow the patient to experience presbyopic correction with the ACUVUE® *BIFOCAL* Contact Lens and to determine the proper lens fit of the contact lenses (see "CRITERIA OF A PROPERLY FIT LENS").

GENERAL FITTING GUIDELINES

Lens Power Selection

A. Initial Distance Power Selection

1. It is very important to determine an accurate distance spectacle Rx; this should be the least minus/most plus refraction that provides the best corrected binocular and monocular visual acuity.
2. Convert the spherocylindrical distance spectacle Rx to a spherical equivalent Rx or conduct a spherical refraction. If the spherical equivalent power is greater than $\pm 4.00D$, a correction for vertex distance will be necessary.
3. For patients with spectacle ADDs ranging from $+0.75D$ to $+2.25D$, insert an ACUVUE® BIFOCAL Contact Lens equal to the patient's spherical equivalent distance Rx (vertex adjusted) determined for each eye.

Note: If the spherical equivalent Rx is calculated to a 0.125D increment, this should be rounded to the more minus/less plus 0.25D contact lens distance power (e.g., if $-3.87D$, fit $-4.00D$; if $+3.87D$, fit $+3.75D$).

Spherical Equivalent

Cylinder	ADD to Sphere Power
-0.25D	-0.25D
-0.50D	-0.25D
-0.75D	-0.50D

4. For patients with a spectacle ADD of $+2.50D$, select a lens with 0.50D more minus power than the spherical equivalent distance Rx (vertex adjusted) of the dominant eye (see "EYE SELECTION" section). For the non-dominant eye, select an ACUVUE® BIFOCAL Contact Lens equal to the spherical equivalent Rx (vertex adjusted).

B. Initial Near (ADD) Power Selection

1. Choose the initial ACUVUE® BIFOCAL ADD Contact Lens equal to the patient's spectacle ADD determined for the preferred reading distance (if between available bifocal lens ADDs, round down to the next lowest ADD).

GENERAL FITTING GUIDELINES

Spectacle ADD ACUVUE® BIFOCAL Contact Lens ADD

$+0.75D$ to $+1.25D$	= $+1.00D$
$+1.50D$ to $+1.75D$	= $+1.50D$
$+2.00D$ to $+2.25D$	= $+2.00D$
$+2.50D$	= $+2.50D$

2. Compare the expected ADD power based on age* and use the lower ADD power:

Age	ACUVUE® BIFOCAL Contact Lens ADD Power
40-46	$+1.00D$
47-52	$+1.50D$
53-59	$+2.00D$
60+	$+2.50D$

* Nominal ADD powers are matched with material presented on pages 338-9 and 803-7 in Benjamin WJ (ed); Borish's CLINICAL REFRACTION (1998) W.B. Saunders Company, Philadelphia.
A patient's individual characteristics should be considered, as well, when the ADD power is determined.

Example 1 (For patients with spectacle ADDs up to $+2.25D$):

A. Initial Distance Power Selection

A 48 year-old patient with a spectacle Rx:

(right eye) = $-3.00D -0.50D \times 180, +1.50D$ ADD

(left eye) = $-2.25D -0.50D \times 170, +1.50D$ ADD

The distance spherical equivalent Rx: (right eye) = $-3.25D$
(left eye) = $-2.50D$

Initial ACUVUE® BIFOCAL Contact Lens distance

power selection: (right eye) = $-3.25D$
(left eye) = $-2.50D$

B. Initial Near (ADD) Power Selection

The patient's near spectacle ADD = $+1.50D$

Initial ACUVUE® BIFOCAL Contact Lens
ADD power selection = $+1.50D$

GENERAL FITTING GUIDELINES

Example 2 (For patients with spectacle ADD of +2.50D):

A. Initial Distance Power Selection

A 63 year-old patient with a spectacle Rx:

(right eye) = -3.00D-0.50D x 180,+2.50D ADD

(left eye) = -2.25D-0.50D x 170,+2.50D ADD

The patient is determined to be right eye dominant.

The distance spherical equivalent Rx: (right eye) = -3.25D
(left eye) = -2.50D

Add more minus power (e.g., -0.50D) to the distance spherical equivalent Rx of the dominant eye.

Initial ACUVUE® BIFOCAL Contact Lens distance power selection:

(right/dominant eye) = -3.75D

(left/non-dominant eye) = -2.50D

B. Initial Near (ADD) Power Selection

The patient's near spectacle ADD = +2.50D

The initial ACUVUE® BIFOCAL Contact Lens ADD power selection = +2.50D

Initial Clinical Assessment

1. Insert the ACUVUE® BIFOCAL Contact Lenses properly (i.e., ensure that the lenses are not inside out).
2. Evaluate the lens fit ensuring that it is acceptable (see "CRITERIA OF A PROPERLY FIT LENS").
3. Allow at least 20 minutes for the patient to adapt to the lenses before evaluating vision.
4. After 20 minutes, ask the patient to binocularly assess his or her distance vision, near vision and position of best focus for near. **NOTE:** For a more accurate assessment, try to simulate the patient's own environment and visual demands (e.g., lighting, print size most typically read, etc.).
5. Measure the binocular and monocular distance VA and near VA at the patient's preferred reading distance.

GENERAL FITTING GUIDELINES

If the lens fit is acceptable (see "CRITERIA OF A PROPERLY FIT LENS"), and the patient obtains acceptable visual performance, the trial lenses should be dispensed for up to one week of wear (see follow-up examinations in the "PATIENT MANAGEMENT" section).

If the patient does not obtain acceptable visual performance, please see the "TROUBLESHOOTING" section.

Troubleshooting (Unacceptable visual performance)

1. Ensure that the lenses have been inserted properly. Some patients will exhibit poor vision from a lens that is inside out, but still report good comfort. If a lens is inside out, remove the lens and insert it properly. Allow the patient to adapt to the lens again before evaluating vision.
2. If lenses were inserted properly, conduct a distance over-refraction to ensure the patient has the least minus/most plus distance correction (i.e., ensure that the patient is not over-minused at distance). If the patient does not have the least minus/most plus distance correction, adjust the prescription and reassess

the visual performance.

3. If the patient does have the least minus/most plus distance correction (i.e., is not over-minused at distance) but has unacceptable visual performance, please follow the flow chart according to the patient's complaint.

Notes:

1. The use of hand-held trial lenses allows for a quick assessment of distance and near vision prior to any lens changes.
2. After a lens change, minor adjustments in distance power may again be required to optimize the visual performance of an individual patient.

GENERAL FITTING GUIDELINES

Vision Optimization

Always have patients keep both eyes open when performing over-refractions.

POOR DISTANCE VISION

1. Present a hand-held trial lens of $\pm 0.25D$ or $\pm 0.50D$ to the dominant eye. If vision improves, change the power of the distance portion of the dominant eye.
2. If vision does not improve, return to the original distance power, but reduce the ADD for the dominant eye by a half diopter.

For high ADD patients see note below.

POOR NEAR VISION

1. Present a hand-held trial lens of $+0.25D$ or $+0.50D$ to the non-dominant eye. If vision improves, change the power to the distance portion of the non-dominant eye.
2. If vision does not improve, return to the original distance power, but increase the ADD for the non-dominant eye by a half diopter.

POOR DISTANCE & NEAR VISION

Address the distance vision first as previously described, and then address the near vision.

Note: For high ADD patients ($+2.50D$). If distance vision is blurry with the initial lens selection containing $-0.50D$ added to the vertex adjusted, spherical equivalent distance prescription of the dominant eye, return to the optimal vertex adjusted, spherical equivalent prescription, but reduce the ADD for the dominant eye by $-1.00D$ (i.e., $+1.50D$).

1. Insert the lens(es) with optimal powers.
2. Assess performance.
3. If good performance, dispense. If poor performance, then go to "ALTERNATIVE FITTING APPROACHES".

ALTERNATIVE FITTING APPROACHES

GENERAL FITTING GUIDELINES

Alternative Fitting Approaches

If distance vision is unacceptable with the fitting options in the "Troubleshooting" section, remove the bifocal lens from the dominant eye only and replace with a single vision lens (e.g., ACUVUE® 2 Brand Contact Lens or ACUVUE® Brand Contact Lens) to maximize distance vision. Consider ACUVUE® Brand *Toric* Contact Lens if astigmatism is equal to or greater than $-0.75D$.

Assess the distance and near vision binocularly and if good performance, dispense.

If near vision is unacceptable, repeat the process for "Poor Near Vision" under "Vision Optimization" and select a bifocal power that is approximately $+0.25$ to $+0.50D$ more plus in the distance power than previously dispensed.

If near vision remains unacceptable, select a new bifocal lens power for the non-dominant eye. The power selection is as follows:

Distance power selection:

For patients with an initial selected

ACUVUE® Brand *BIFOCAL* Contact Lens ADD of $+1.50D$ or less, add $+0.50D$ to the distance spherical equivalent Rx. For patients with an initial selected ACUVUE® *BIFOCAL* Contact Lens ADD of $+1.75D$ or greater, add $+0.75D$ to the distance spherical equivalent Rx.

Near power selection:

Initial ACUVUE® <i>BIFOCAL</i> Contact Lens Selected ADD	New ACUVUE® <i>BIFOCAL</i> Contact Lens ADD
$+1.00D$ to $+1.50D$	= $+1.00D$
$+2.00D$	= $+1.50D$
$+2.50D$	= $+2.00D$

Example:

A 56 year old patient with a spectacle Rx:
 (right eye) = $+2.00D-0.50D \times 180$,
 $+2.00D$ ADD
 (left eye) = $+2.25D-0.50D \times 170$,
 $+2.50D$ ADD

The patient is determined to be right eye dominant.

GENERAL FITTING GUIDELINES

The distance spherical equivalent Rx:
(right eye) = +1.75D
(left eye) = +2.00D

The dominant eye is fit with a single vision contact lens (e.g., ACUVUE®2 Contact Lens or ACUVUE® Contact Lens) equal to the distance spherical equivalent Rx.

Dominant eye (distance lens), single vision power selection:

1. Initial ACUVUE®2 Contact Lens or ACUVUE® Contact Lens power selection for the right eye is +1.75D.

Non-dominant eye (near lens) bifocal power selection:

1. Follow the troubleshooting section for near vision. Adjust the bifocal power to +2.25D/+2.00D or +2.50D/+2.00D ADD for the left eye.
2. If near vision is still unacceptable, remove the bifocal lens and adjust the distance and near power. For this patient, the bifocal power selection would be +2.75D/+1.50D.

Initial Clinical Assessment

1. Insert the single vision ACUVUE® Contact Lens, ACUVUE®2 Contact Lens or ACUVUE® TORIC Contact Lens and the ACUVUE® BIFOCAL Contact Lens properly (i.e., ensure that the lenses are not inside out).
2. Evaluate the lens fit ensuring that the lens fit is acceptable (see "CRITERIA OF A PROPERLY FIT LENS").
3. Allow lens to equilibrate to eye.
4. Ask the patient to binocularly assess their distance vision, near vision and position of best focus for near. **NOTE:** For a more accurate assessment, try to simulate the patient's own environment and visual demands (e.g., lighting, print size most typically read, etc.).
5. Measure the binocular and monocular distance VA and near VA at the patient's preferred reading distance.

GENERAL FITTING GUIDELINES

If the lens fit is acceptable (see "CRITERIA OF A PROPERLY FIT LENS"), and the patient obtains acceptable visual performance, the trial lenses should be dispensed for up to one week of wear (see follow-up examinations in the "PATIENT MANAGEMENT" section).

If the patient reports visual difficulties, ensure that the lenses have been properly inserted and then use hand-held trial lenses to adjust the distance power in one or both eyes until an acceptable balance between distance and near is achieved. Insert new lenses and confirm performance. If the patient's vision is still not acceptable, consider Monovision.

Eye Selection

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

A. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "sighting eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

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

Other methods include the refractive error method and the visual demands method.

GENERAL FITTING GUIDELINES

B. Refractive Error Method

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

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 function best with the near lens on the left eye.

Criteria of a Properly Fit Lens

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

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when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

Characteristics of a steep (tight) lens

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

Characteristics of a flat (loose) lens

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

The lens fit for the ACUVUE® BIFOCAL Contact Lens should meet the CRITERIA OF A PROPERLY FIT LENS to ensure optimal lens performance.

GENERAL FITTING GUIDELINES

Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, fluctuating vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the symptoms related to adaptation to the patient. These symptoms may last for a 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.

During the adaptation process, it is advisable to caution patients about driving an automobile, until the patient feels comfortable that their vision will not compromise their driving performance. This is particularly true for 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.

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PATIENT MANAGEMENT

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® Brand *BIFOCAL* Contact Lens PATIENT INSTRUCTIONS (DISPOSABLE AND 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 disinfection (including hydrogen peroxide) is recommended. Heat disinfection is not advised.

- Review the Package Insert for the ACUVUE® *BIFOCAL* (etafilcon A) Contact Lens and provide the patient with all of the relevant information and precautions on the proper use of the ACUVUE® *BIFOCAL* 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® *BIFOCAL* Contact Lens for Daily Wear 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, binocularly and monocularly, at distance and near with the contact lenses.
3. Perform an over-refraction at distance and near.

PATIENT MANAGEMENT

4. With the biomicroscope, judge the lens fitting characteristics (as described in the "CRITERIA OF A PROPERLY FIT LENS") and evaluate the lens surface for deposits and damage.
5. Following lens removal, examine the cornea and conjunctiva with a 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, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
 - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
6. Periodically perform keratometry and spectacle refractions. The values should be recorded and compared to the baseline measurements.

PATIENT MANAGEMENT

If any observations are abnormal, use professional judgment 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" of 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® Brand BIFOCAL 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
1-800-843-2020

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.

NOTES

Horizontal lines for notes.

NOTES

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NOTES

Lined area for notes on the right page, consisting of 20 horizontal lines.

NOTES

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)
 WITH UV BLOCKER
 For Daily Wear

SUREVUE® Contact Lens

(etafilcon A)
 VISIBILITY TINTED WITH UV BLOCKER
 For Daily Wear

VISTAKON®

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