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 eve for the continued health of the eve. 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 Eve 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.

turer and/or 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

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

GENERAL LENS CARE
(To first clean and rinse, then disinfect lenses)

. Use the recommended system of lens care, chemical (not heat), and carefully fol-

low instructions on solution labeling. Different solutions cannot always be used

Do not use saliva or anything other than the recommended solutions for lubricat-

· 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 sur-

scribed 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

The Eye Care Professional should recommend a care system that is appropriate

for the VISTAKON® (etafilcon A) contact lenses prescribed on a frequent replace-

ment schedule. Each lens care product contains specific directions for use and

Note: Some solutions may have more than one function, which will be indicat-

• Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens

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-

thoroughly with recommended saline or disinfecting solution to remove the cleaning

ed on the label. Read the label on the solution bottle, and follow instructions.

important safety information, which should be read carefully and followed.

· Always remove, clean, rinse and disinfect lenses according to the schedule pre-

together and not all solutions are safe for use with all lenses. Do not alternate or

· Always wash, rinse and dry hands before handling contact lenses.

mix lens care systems unless indicated on solution labeling.

ing or rewetting lenses. Do not put lenses in the mouth.

face. Disinfecting is necessary to destroy harmful germs.

Always use fresh unexpired lens care solutions.

with disposable lenses. Patients should always dispose of lenses when they are

removed and have replacement lenses or spectacles available.

recommended for the patient.

Frequent replacement lenses

not substitute for disinfection

**Basic Instructions** 

- . To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the Package Insert or the Eye Care Professional for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage. case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals, as recommended by the lens case manufacturer or your Eye Care Professional.
- Eye Care Professionals may recommend a lubricating/rewetting solution that 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, disinfect by carefully following the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the Eve Care Professional.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system
- . Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution
- 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

· 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, 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 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 eve 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 IMMEDIATE-LY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

#### HOW SUPPLIED

ACUVUE® Brand, ACUVUE® 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 eve 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:

"ACUVUE" Brand and ACUVUE" 2 and ACUVUE® 2 Lenses Brand Contact Lenses Fitting and Patient Management Guide'

ACUVUE® 2 COLOURS™ "ACUVUE® 2 COLOURS™ Brand Contact Lenses Fitting and Patient

Management Guide 1.DAY ACUVUE® "1.DAY ACUVUE" Brand Contact Lens

and 1. DAY ACUVUE® MOIST™ Fitting and Patient Management Guide' ACUVUE® BIFOCAL "ACUVUE" Brand BIFOCAL Contact Lens Fitting and Patient Management Guide'

"ACUVUE" Brand TORIC Contact Lens Fitting ACUVUE® TORIC Lens and Patient Management Guide SUREVUE® Lens "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

### 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 then 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

#### 1. DAY ACUVUE® Brand Contact Lenses:

Fach 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



Revision date Dec 2005 www.acuvue.com

Global copy clearance number: M05463 Made in the U.S.A Revision Number: M-02-06-02

ACUVUE®, ACUVUE® 2 COLOURS™, 1. DAY ACUVUE® MOIST™, SUREVUE® and VISTAKON® are trademarks of Johnson & Johnson Vision Care, Inc.

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

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 Eve 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 :

рау	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 eves 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 natients 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** 

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

SUREVUE® Contact Lens

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



ACUVUE® Brand, ACUVUE® Brand, ACUVUE® Brand BIFOCAL, ACUVUE® Brand TORIC. 1•DAY ACUVUE® MOIST™ Brand and SUREVUE® (etafilcon A) SOFT (HYDROPHILIC) CONTACT LENSES - VISIBILITY TINTED WITH UV BLOCKER

1. DAY ACUVUE® Brand (etafilcon A) SOFT (HYDROPHILIC) CONTACT LENSES -CLEAR AND VISIBILITY TINTED WITH UV BLOCKER

ACUVUE®2 COLOURS™ Brand, SOFT (HYDROPHILIC) CONTACT LENSES WITH UV BLOCKER

	SAMR
SYMBOL	DEFINITION
<u>A</u>	See Instruction Leaflet
	Use By Date (expiration date)
LOT	Batch Code
STERLE	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
C€ 0086	Quality System Certification Symbol
Park (i)	UV Blocking
0	Fee Paid for Waste Management
3	Peel Back Foil
<b>R</b> Only	Caution: Federal law restricts this device to sale by or on the order of a licensed practitione
ACUVUE* L	enses
- OX	Visibility Tinted Lens Orientation Correct
·	Visibility Tinted Lens Inside Out
1.DAY ACU ACUVUE® B	VUE®, 1•DAY ACUVUE® MOIST™, ACUVUE® 2 and IFOCAL Lenses
OX.	Visibility Tinted Lens Orientation Correct
₩.	Visibility Tinted Lens Inside Out
ACUVUE® 7	TORIC Lenses
CYL	Cylinder Power
AXIS	Axis
ACUVUE® 2	COLOURS™ Lenses
0-GRY	Opaque Gray
0-GRN	Opaque Green

O-HNY Opaque Honey

O-CHN Opaque Chestnut

O-SPH Onaque Sannhire O-BLU Opaque Blue

O-HZL Opaque Hazel

E-AQU Enhancer Aqua E-BLU Enhancer Blue E-GRN Enhancer Green The following symbols may appear on the labels or cartons of ACUVUE® Brand, ACUVUE® 1.0AV Brand, ACUVUE® 1.0AV Brand, ACUVUE® 2 COLOURS™ Brand, 1.DAY ACUVUE® Brand. 1.DAY ACUVUE® MOIST™ Brand, ACUVUE® Brand BIFOCAL, ACUVUE® Brand TORIC, and SUREVUE® Contact Lenses with UV Blocker.

Spherical Lenses For: Myopia, Hyperopia, Aphakic or Not-Aphakic ACUVUE®, ACUVUE®2, ACLIVITE® 2 COLOURSTM 1. DAY ACUVUE®. 1.DAY ACUVUE® MOIST

Bifocal Lenses For: Presbyopia, Aphakic or Not-Aphakic ACUVUE® BIFOCAL Lenses

Toric Lenses For: Myopic Astigmatism, Hyperopic Astigmatism Aphakic or Not-Aphakic ACUVUE® TORIC Lenses

SYMBOLS KEY

 Specific Gravity (calculated): ACUVUE®, ACUVUE®2, ACUVUE® BIFOCAL, ACUVUE® TORIC, 1. DAY ACUVUE®, 1. DAY ACUVUE® MOIST™, and Refractive Index: 1.40

•Visible Light Transmission: 85% minimum, visibility tint 95% minimum, clear greater than 70%, color

·Surface Character: Hydrophilic

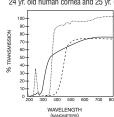
•Water Content: 58%

Oxygen Permeability:

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

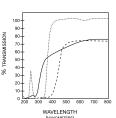
## TRANSMITTANCE CURVE

ACUVUE® Brand (etafilcon A) Contact Lens Visibility Tinted with UV Blocker. 24 yr. old human cornea and 25 yr. old human crystalline lens



- ... ACUVUE® Brand (etafilcon A) Disposable Contact Lens With Visibility Tint and UV Blocker \_\_\_\_24 YR OLD HUMAN CORNEA<sup>1</sup>
- ... 25 YR OLD HUMAN CRYSTALLINE LENS?
- \* The data was obtained from measurements taken through the central 3-5mm portion for the hinnest marketed lens (-3.00D ACUVUE® Brand Contact Lens, 0.070mm center thickness) . Lerman, S., Radiant Energy and the Eye, MacMillan
- New York 1980 n 58 figure 2-21 2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida,

ACUVUE® 2 COLOURS™ Brand, (etafilcon A) Contact Lens with UV Blocker (Opaque), 24 yr. old human cornea and 25 yr. old human crystalline lens



- .. ACUVUE® 2 COLOURS™ Brand (etafilcon A) Contact Lens'
- \_\_\_24 YR OLD HUMAN CORNEA<sup>1</sup>
- \_\_ 25 YR OLD HUMAN CRYSTALLINE LENS<sup>2</sup>
- \* The data was obtained from measurements taken through the central 3-5mm portion for the thinnest marketed lens (-3.00D ACUVUE 2 COLOURS™ Brand Contact Lenses, 0.084mm center thickness).
- Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
- 2 Waxler M Hitchins V.M. Ontical Badiation 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.

#### DESCRIPTION

The ACUVUE® Brand, ACUVUE®2 Brand, ACUVUE®2 COLOURS™ Brand, 1•DAY ACU VUE® Brand, 1•DAY ACUVUE® MOIST™ Brand, and SUREVUE® (etafilcon A) soft (hydrophilic) Contact Lenses are available as spherical lenses; the ACUVUE® Brand BÍFOCAL (etafilcon A) soft (hydrophilic) Contact Lens is available as a spherical bifo cal lens; and the ACUVUE® Brand TORIC (etafilcon A) soft (hydrophilic) Contact Lens is available as a toric 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®, ACUVUE® 2, 1 • DAY ACUVUE®, 1 • DAY ACUVUE® MOIST™, ACUVUE® BIFOCAL, ACUVUE® TORIC and SUREVUE® Lenses with Visibility Tint are tinted blue using Reactive Blue Dye #4 to make the lenses more visible for handling. The ACUVUE®2 COLOURSTM, Contact Lenses contain a pigmented area that will mask or enhance the color of the natural iris. The lens is colored with one or more of the following color additives; iron oxides, titanium dioxide, phthalocvaninato (2-) copper, phytalocvanine green, vat orange 1 and Reactive Blue Dye #4. The ACUVUE®2 COLOURS™ Brand lens is available in the following opaque colors; Blue, Gray, Green, Honey, Chestnut, Hazel and Sapphire. They are also available in the following enhancer colors: Blue, Green and Aqua. A benzotriazole UV absorbing monomer is used to block UV radia-

The UV Blocking averages:

in the range of	316nm to 380nm	280nm to 31
ACUVUE® Lenses	82%	97%
1.DAY ACUVUE® Lenses	82%	97%
1•DAY ACUVUE® MOIST™ Lenses	82%	97%
ACUVUE® 2 Lenses	88%	99%
ACUVUE® 2 COLOURS™ Lenses	81%	97%
ACUVUE® BIFOCAL Lenses	86%	98%
ACUVUE® TORIC Lenses	85%	97%
SUREVUE® Lenses	87%	99%

The physical/optical properties of the lens are:

SUREVUE® Lenses: 0.98 - 1.12 ACUVUE® 2 COLOURS™ Lens: 0.98 - 1.13

#### ACTIONS

In its hydrated state, the VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retinal

The average UV Blocking for the ACUVUE® Lens, ACUVUE® 2 COLOURS™ Lens, 1•DAY ACUVUE® Lens, 1•DAY ACUVUE® MOIST™ Lens, ACUVUE® BFOCAL Lens, ACUVUE® TORIC Lens or SUREVUE® Lens with UV Blocker is a table of the control of the contro

	UVA	UVB
ACUVUE® Lens	82%	97%
ACUVUE® 2 Lens	88%	99%
ACUVUE® 2 COLOURS™ Lens	81%	97%
1•DAY ACUVUE® Lens	82%	97%
1•DAY ACUVUE® MOIST™ Lens	82%	97%
ACUVUE® BIFOCAL Lens	86%	98%
ACUVUE® TORIC Lens	85%	97%
SUREVUE® Lens	87%	99%

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

#### INDICATIONS (USES)

The indications are described by brand name below. The definitions of daily wear and extended wear within these indications statements follow:

EXTENDED WEAR: One to 7 days/ 6 nights of continuous wear including while asleep. DAILY WEAR: Periods of less than 1 day of wear while awake.

The ACUVUE® Brand and ACUVUE®2 Brand Contact Lenses (spherical) are indicated for daily and extended wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1 00D or less astigmatism

The ACUVUE®2 COLOURS™ Brand Contact Lens is indicated for daily and extendedwear to enhance or alter the apparent color of the eye and/or for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons, withnon-diseased eyes who may have 1.00D or less of astigmatism.

The 1.DAY ACUVUE® Brand Contact Lens (spherical) is indicated for daily disposable wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D or less of astigma-

The 1•DAY ACUVUE® MOIST™ Brand Contact Lens (spherical) is indicated for daily disposable wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

METHOD

The ACUVUE® Brand, ACUVUE® 2 Brand, ACUVUE® 2 COLOURS™ Brand, 1•DAY ACUVUE® Brand, 1•DAY

ACUVUE® MOIST™ Brand, ACUVUE® Brand BIFOCAL and SUREVUE® Contact Lenses are hemispherical

ACUVUE® BIFOCAL, ACUVUE® TORIC, and SUREVUE® Contact Lenses . . . . (12.0 mm to 15.0 mm)

shells; the ACUVUE® Brand TORIC Lens is a hemitoric shell; of the following dimensions:

ACUVUE® 2, 1•DAY ACUVUE® , 1•DAY ACUVUE® MOIST™ (Visibility Tinted),

ACUVUE®, ACUVUE® 2, 1•DAY ACUVUE®, 1•DAY ACUVUE® MOIST™ (Visibility Tinted),

ACTIVITE® ACTIVITE® 2 ACTIVITE® 2 COLOURS™ 1.0AY ACTIVITE® 1.0AY ACTIVITE® MOIST™

1.DAY ACUVUE® (Clear) and SUREVUE® Lenses ......(e.g., +3.00D: 0.200mm)

1•DAY ACUVUE®, 1•DAY ACUVUE® MOIST™ Lenses .....-20.00D to +20.00D

ACUVUE® 2 COLOURS™ Lenses .....

ACUVUE® 2 COLOURS™ Lenses .....

ACUVUE® BIFOCAL, ACUVUE® TORIC, SUREVUE® Lenses ......

ACUVUE®. ACUVUE® 2 and ACUVUE® 2 COLOURS™Lenses

ACUVUE®, ACUVUE®2, ACUVUE®2 COLOURS™, 1•DAY ACUVUE®, 1•DAY ACUVUE® MOIST™,

Fatt (boundary corrected.

Fatt (boundary corrected

. .(e.g., -3.00D: 0.070mm)

. .(e.g., -3.00D: 0.084mm)

. .(e.g., -3.00D: 0.075mm)

. .(e.g., -3.00D: 0.105mm)

. .(e.g., +3.00D: 0.170mm)

. .(e.g., +3.00D: 0.131mm)

. . . . . (7.85mm to 10.00mm)

.-20.00D to +20.00D

-20.00D to +20.00D

. .-20.00D to +14.00D

non-edge corrected)

edge corrected)

VALUE 28.0 x 10<sup>-11</sup> (cm<sup>2</sup>/sec)

(ml O<sub>2</sub>/ml x mm Hg) at 35°C

(ml O<sub>2</sub>/ml x mm Hg) at 35°C

low minus lens - varies with power

ACUVUE® TORIC Lenses

SURFVUF® Lenses

plus lens - varies with power

ACUVUE® TORIC Lenses

SUREVUE® Lenses .

Daily Wear

Extended Wear

ACUVUE®, 1. DAY ACUVUE®, (Clear)

ACUVUE® BIFOCAL Lenses .....

21.4 x 10<sup>-11</sup> (cm<sup>2</sup>/sec)

Center Thickness

Base Curve

Power

The ACUVUE® Brand BIFOCAL Contact Lens is indicated for daily and 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. The ACUVUE® Brand TORIC Contact Lens is indicated for daily and extended wear for the correction of visual acuity in aphabic or not-aphabic persons with non-diseased eyes who are hyperopic or myopic and may have 0.50D to 2.50D of astigmatism.

The SUREVUE® Contact Lens (spherical) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. The ACUVUE® ACUVUE® 2, ACUVUÉ® 2 COLOURS™, ACUVUE® BIFOCAL, ACUVUE® TORIC, 1•DAY ACUVUE®, 1. DAY ACUVUE® MOIST™, and SUREVUE® Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

#### Frequent Replacement Wear:

When prescribed for frequent/planned replacement wear (see "WEARING SCHED-ULE") the VISTAKON® (etafilcon A) contact lens is to be cleaned, rinsed and disinfected each time the lens is removed. The etafilcon A contact lens is to be discarded after the recommended wearing period prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the VISTAKON® (etafilcon A) contact lens may be disinfected using a chemical disinfection system only.

#### Disposable Wear:

When prescribed for single-use disposable wear (see "WEARING SCHEDULE") the VISTAKON® (etafilcon A) contact lens is to be discarded after each removal. 1. DAY ACUVUE®, and 1•DAY ACUVUE® MOIST™ Brand Contact Lenses are to be prescribed for daily disposable wear and is to be discarded after each removal.

## **CONTRAINDICATIONS (REASONS NOT TO USE)**

DO NOT USE the ACUVUE® Brand, ACUVUE® 2 Brand, ACUVUE® 2 COLOURS™ Brand, 1. DAY ACUVUE® Brand, 1. DAY ACUVUE® MOIST™ Brand, ACUVUE® Brand BIFOCAL, ACUVUE® Brand TORIC or SUREVUE® Contact Lens when any of the following conditions exist:

- Acute or subacute inflammation or infection of the anterior chamber of the eve. · Any eye disease, injury or abnormality that affects the cornea, conjuctiva or eyelids
- · Severe insufficiency of lacrimal secretion (dry eyes)
- · Corneal hypoethesia (reduced corneal sensitivity), if not-aphakic

ACUVUE® BIFOCAL Lenses
Daily Wear20.00D to +20.00D
Extended Wear20.00D to +14.00D
Bifocal ADD Powers+0.25D to +4.00D
Bifocal ADD Power Diameters
ACUVUE® TORIC Lenses
Daily Wear20.00D to +20.00D
Extended Wear20.00D to +14.00D
Cylinder Power0.25D to -10.00D
Axis

Base Curve	<u>Diameter</u>	Power Range
ACUVUE®Brand Contact	Lens	
Minus		
8.4mm, 8.8mm	14.0mm	-0.50D to -6.00D (in 0.25D increments) -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)
ACUVUE® 2 Brand Conta	ct Lens	
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)
ACUVUE® 2 COLOURS™	Brand Contact Lens	
Minus		
8.3mm, 8.7mm Enhancers	14.0mm	Plano -0.25D to -6.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments)
8.3mm, Opaques	14.0mm	Plano -0.25D to -6.00D (in 0.25D increments)
Plus		-6.50D to -9.00D (in 0.50D increments)
8.3mm, 8.7mm Enhancers	14.0mm	+0.25D to +6.00D (in 0.25D increments)
8.3mm, Opaques	14.0mm	+0.25D to +6.00D (in 0.25D increments)

ACUVUE® BIFO	CAL Lenses	
		20.00D to +20.00D
		20.00D to +14.00D
		+0.25D to +4.00D
Bifocal ADD Power Diameters		1.8 to 13.0mm
ACUVUE® TORI	C Lenses	
		20.00D to +20.00D
Extended Wear		20.00D to +14.00D
		0.25D to -10.00D
Cylinder Power		

ACUVUE®Brand Contact	Lens	
Minus		
8.4mm, 8.8mm	14.0mm	-0.50D to -6.00D (in 0.25D increments) -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
ACUVUE® 2 Brand Conta	ct Lens	
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
ACUVUE® 2 COLOURS™	Brand Contact Len	<u>s</u>
Minus		
8.3mm, 8.7mm Enhancers	14.0mm	Plano -0.25D to -6.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments)
8.3mm, Opaques	14.0mm	Plano -0.25D to -6.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments)
Plus		-0.30D to -9.00D (III 0.30D IIICIEIIEIIS)
8.3mm, 8.7mm Enhancers	14.0mm	+0.25D to +6.00D (in 0.25D increments
	14.0mm	+0.25D to +6.00D (in 0.25D increments

ACUVUE®Brand Contact Le	ns	
Minus		
8.4mm, 8.8mm	14.0mm	-0.50D to -6.00D (in 0.25D increments) -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)
ACUVUE® 2 Brand Contact	<u>Lens</u>	
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)
ACUVUE® 2 COLOURS™ Br	and Contact Lens	
Minus		
8.3mm, 8.7mm Enhancers	14.0mm	Plano -0.25D to -6.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments)
8.3mm, Opaques	14.0mm	Plano -0.25D to -6.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments)
Plus		-0.30D to -3.00D (III 0.30D IIICIEIIIEII3)
8.3mm, 8.7mm Enhancers	14.0mm	+0.25D to +6.00D (in 0.25D increments)
8.3mm, Opaques	14.0mm	+0.25D to +6.00D (in 0.25D increments)

· Any systemic disease that may affect the eye or be exaggerated by wearing

ed by wearing contact lenses or use of contact lens solutions

· Any active corneal infection (bacterial, fungal, protozoal or viral)

Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerat-

· Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to

beused to care for the lenses prescribed on a frequent replacement wear schedule.

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

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of

• 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 per-

lens users than for daily wear users. When daily wear users who wear their lens-

es 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

· When daily wear users wear their lenses overnight (outside the approved indica-

tion), the risk of ulcerative keratitis is 9 times greater than among those who do

The overall risk of ulcerative keratitis may be reduced by carefully following direc-

· The risk of ulcerative keratitis among contact lens users who smoke is estimated

If patients experience eye discomfort, excessive tearing, vision changes, redness of

the eye or other problems, they should be instructed to immediately remove their

lenses and promptly contact their Eye Care Professional. It is recommended that

contact lens wearers see their Eye Care Professional routinely as directed.

The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact.

the safe use of these products. Patients should be advised of the following

# 8.5mm, 9.0mm ACUVUE® Brand BIFOCAL Contact Lens 8.5mm ADD Powers ACUVUE® Brand TORIC Contact Lens 8.7mm Plus 8.7mm SUREVUE® Contact Lens 8.4mm, 8.8mm

9.1mm

1.DAY ACUVUE® Brand Contact Lens

1. DAY ACUVUE® MOIST™ Brand Contact Lens

14.2mm

14.2mm

14.2mm

14.2mm

14.4mm

14.4mm

14.0mm

14.4mm

-0.50D to -6.00D (in 0.25D increments)

+0.50D to +6.00D (in 0.25D increments)

-0.50D to -6.00D (in 0.25D increments) -6.50D to -12.00D (in 0.50D increments)

+0.50D to +6.00D (in 0.25D increments)

+6.00D to -9.00D (in 0.25D increments)

+1.00D to +2.50D (in 0.50D increments)

Plano to -6.00D (in 0.25D increments) Cylinders -.75D, -1.25D, -1.75D Axis 10° to 180° (in 10° increments)

-6.50D to -9.00D (in 0.50D increments)

+0.25D to +6.00D (in 0.25D increments)

-0.50D to -6.00D (in 0.25D increments)

+0.50D to +6.00D (in 0.25D increments)

Cylinders -1.25 and -1.75 D Axis 10°, 20°, 70°, 80°, 90°, 100°, 110°,160°, 170°, 180°

Cylinders -.75D, -1.25D, -1.75D Axis 10°, 20°, 70°, 80°, 90°, 100°, 110°,160°, 170°, 180°

Labeled Power=Measured ADD Power -0.50D

8.5mm, 9.0mm

8.5mm, 9.0mm

8.5mm, 9.0mm

Plus

Plus

## PRECAUTIONS

Special Precautions for Eye Care Professionals

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness and optic zone diameter. The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.
- . DO NOT use if the sterile blister package is opened or damaged.
- Patients who wear VISTAKON® (etafilcon A) contact lenses to correct preshyonia using Monovision or patients who use the ACUVUE® Brand BIFOCAL Contact Lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements may vary with the individual and should be considered when selecting the most appropriate type of lens for each natient
- Due to the reduction in light transmittance with cosmetically tinted lenses, some patients may experience visual symptoms while wearing ACUVUE®2 COLOURS™ Brand Contact Lenses, Brand Contact Lenses. In addition, some patients may
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dve and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- . Before leaving the Eye Care Professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated. Eye Care Professionals should carefully instruct frequent replacement lens wear patients about the following care regimen and safety precautions:

- 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 Insert for the use of contact

1 New England Journal of Medicine, September 21, 1989

not wear them overnight.

contact lenses

· If eyes become red or irritated

warnings pertaining to contact lens wear:

sons in extended wear contact lens users.

times greater than among daily wear users.

tions for lens care, including cleaning the lens case.

to be 3 to 8 times greater than among non-smokers.

vision. The results of a study indicate the following: