

Patient Instruction Guide

Disposable Daily And Extended Wear

VISTAKON® (etafilcon A)

Contact Lenses

CLEAR AND VISIBILITY TINTED WITH UV BLOCKER














For Disposable Daily And Extended Wear

VISTAKON®

DIVISION OF
Johnson & Johnson
Vision Care, Inc.

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
	Quality System Certification Symbol
	UV Blocking
	Peel Back Foil
	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
C. T.	Center Thickness
	Visibility Tinted Lens Orientation Correct
	Visibility Tinted Lens Inside Out
	Visibility Tinted Lens Orientation Correct
	Visibility Tinted Lens Inside Out
	Fee Paid for Waste Management

PATIENT INSTRUCTIONS for VISTAKON® (etafilcon A)

Soft (hydrophilic) Contact Lenses

Introduction	1
Wearing Restrictions and Indications	2
Contraindications	3
Warnings	3-4
Precautions	4-5
Adverse Reactions	5-6
Personal Cleanliness for Lens Handling and Insertion	6
Preparing the Lens for Wearing	6
Opening The Multipack and Lens Package	7
Handling the Lenses	7
Placing the Lens on the Eye	7-8
Centering the Lens	9
Removing the Lens	9-10
Caring for Your Lenses	10
Care for a Sticking (non-moving) Lens	10
Emergencies	10
Instructions for the Presbyopic Patient (Monovision)	10-11
Wearing and Appointment Schedules	13
Patient/Eye Care Professional Information	14

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

INTRODUCTION

Congratulations on choosing the VISTAKON® (etafilcon A) Soft (hydrophilic) Disposable Contact Lens Clear and Visibility Tinted with UV Blocker for Daily and Extended Wear. In the VISTAKON® (etafilcon A) Contact Lenses Clear and Visibility Tinted with UV Blocker, a UV absorbing monomer is used to block UV radiation. When your prescribed daily or extended wearing time is over, you simply throw the used lens away and replace it with a new sterile one. By replacing your VISTAKON® (etafilcon A) Contact Lens as prescribed, there is little chance for long-term build-up, which can affect vision and cause irritation and discomfort to the eye. VISTAKON® (etafilcon A) Disposable Contact Lenses are single-use and are to be removed and discarded as prescribed by your Eye Care Professional. You should always have replacement lenses or spectacles available.

The VISTAKON® (etafilcon A) Disposable Contact Lenses are soft spherical lenses. They are made from a “water-loving”(hydrophilic) material that has the ability to absorb water, making the lens soft and flexible. They differ from other lenses available because of the way they are manufactured. Simply put, the multi-patented manufacturing process which took years to perfect, makes VISTAKON® (etafilcon A) Contact Lens disposable wear possible. Since the lenses are produced identically one after another, you will experience the same excellent comfort and vision, lens after lens after lens.

The information and instructions contained in this booklet apply only to the VISTAKON® (etafilcon A) Disposable Contact Lenses. The VISTAKON® (etafilcon A) Disposable Contact Lenses are intended to be used for daily and extended wear within the VISTAKON® planned lens replacement system. For your eye health, it is important that the VISTAKON® (etafilcon A) Disposable Contact Lenses be worn, as prescribed by your Eye Care Professional. Your Eye Care Professional should be kept fully aware of your medical history. Your Eye Care Professional will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling, including how to safely and easily open the packaging. You will also be instructed on how to properly insert and remove lenses. This booklet will reinforce those instructions. VISTAKON® (etafilcon A) Disposable Contact Lenses should be discarded and replaced with a new sterile pair, as prescribed by your Eye Care Professional. If you have any questions, always ask your Eye Care Professional.

WEARING RESTRICTIONS AND INDICATIONS

The VISTAKON® (etafilcon A) 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 of astigmatism or less.

VISTAKON® (etafilcon A) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The VISTAKON® (etafilcon A) Contact Lenses described in this booklet may be prescribed for either daily wear or extended wear from 1-7 days between removal as recommended by your Eye Care Professional. They should be removed from your eyes and discarded as prescribed by your Eye Care Professional.

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 Professional for more information.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE THE VISTAKON® (etafilcon A) Contact Lenses 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 not-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
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS

Problems with contact lenses could result in serious injury to the eye. Proper use and care of contact lenses are essential for the safe use of these products. The following warnings pertain to contact lens wear:

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. The results of a study¹ 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 approval 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.

¹ New England Journal of Medicine, September 21, 1989

- 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 you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, you should immediately remove your lenses and promptly contact your Eye Care Professional. It is recommended that you see your Eye Care Professional routinely, as directed.

PRECAUTIONS

- DO NOT use if the sterile blister package is opened or damaged.
- Patients who wear contact lenses to correct presbyopia using Monovision may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens.
- Before leaving the Eye Care Professional's office, you should be able to promptly remove lenses, or you should have someone else available who can remove the lenses for you.
- You should remove your lenses immediately if your eyes become red or irritated.
- If the lens sticks (stops moving) on your eye, follow the recommended directions in "Care for a Sticking Lens". The lens should move freely on your eye for the continued health of your eye. If non-movement of your lens continues, you should immediately consult your Eye Care Professional.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on your lenses. It is best to put on your lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch your contact lenses with your fingers or hands if they are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in this booklet and those prescribed by your Eye Care Professional.
- Never wear your lenses beyond the period recommended by your Eye Care Professional.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep your 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 lenses during sporting activities.
- Inform your doctor (Health Care Practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Slide the lens up the side of the bowl.
- Do not touch the lens with your fingernails.
- Always discard lenses as prescribed by your Eye Care Professional.
- Always contact your Eye Care Professional before using any medicine in your eyes.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you 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 lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes.

ADVERSE REACTIONS (Problems And What To Do)

The following problems may occur when wearing contact lenses:

- Your eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on your eye.
- There may be a feeling of something in your 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 your eye.
- Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia or dry eyes may also occur if your lenses are worn continuously or for too long a time.

You should conduct a simple 3-part self-examination at least once a day. Ask yourself:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Do I continue to see well?

If you report any problems, you should IMMEDIATELY REMOVE YOUR LENS.

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

If the lens is in any way damaged, you SHOULD NOT put the lens back on your eye. You should discard the lens and insert a new fresh lens on your eye.

If your lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, you should dispose of the lens and insert a new fresh lens.

If the problem continues, you SHOULD NOT put the lens back on your eye but IMMEDIATELY CONSULT YOUR EYE CARE PROFESSIONAL.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS FOR LENS HANDLING AND INSERTION

1. Preparing the Lens for Wearing

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Opening the Multipack and Lens Package

Multipack

It is simple to open the multipack. Locate the opening flap on the front of the multipack and pull up to break the seal. Each lens comes in its own lens package designed specifically to maintain sterility. To close the multipack for storage, just tuck in the flap.

Lens Package

To open an individual lens package, follow these simple steps:

1. Shake the lens package and check to see that the lens is floating in the solution.
2. Peel back the foil closure to reveal the lens. By stabilizing the lens package on the tabletop, you will minimize the possibility of a sudden splash.

Occasionally, a lens may adhere to the inside surface of the foil when opened, or to the plastic package itself. This will not affect the sterility of the lens. It is still perfectly safe to use. Carefully remove and inspect the lens following the handling instructions.

3. Handling the Lenses

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears. If the lens appears damaged, do not use it. Use the next lens in the multipack.

Verify that the lens is not turned inside out by placing it on your forefinger and checking its profile. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out. Another method is to gently squeeze the lens between the thumb and forefinger.

The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.

Place the lens on your forefinger and, looking up at the lens, locate the letters AV or the numbers 123. AV or 123 indicates correct orientation while VA or a reverse 123 indicates the lens is inside out. If the lens is inside out (VA or a reverse 123), invert the lens and locate the letters or numbers again to confirm correct lens orientation.

4. Placing the Lens on the Eye.

Remember, start with your right eye.

Once you have opened the lens package, removed and examined the lens, follow these steps to apply the lens to your eye:

1. Place the lens on the tip of your forefinger. BE SURE THE LENS IS CORRECTLY ORIENTED (see "Handling the Lenses").
2. Place the middle finger of the same hand close to your lower eyelashes and pull down the lower lid.
3. Use the forefinger or middle finger of the other hand to lift the upper lid.
4. Place the lens on the eye.
5. Gently release the lid and blink. The lens will center automatically.
6. Use the same technique when inserting the lens for your left eye.

There are other methods of lens placement. If the above method is difficult for you, your Eye Care Professional will provide you with an alternate method.

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the Lens", next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
 - a. Cosmetics or oils on the lens. Dispose of the lens and insert a new fresh lens.
 - b. The lens is on the wrong eye.
 - c. The lens is inside-out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your Eye Care Professional.

If a lens becomes less comfortable than when it was first inserted or if it is markedly uncomfortable upon insertion, remove the lens immediately and contact your Eye Care Professional.

After you have successfully inserted your lenses, you should ask yourself:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Do I see well?

If your examination shows any problems, IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYE CARE PROFESSIONAL.

5. Centering the Lens

A lens which is on the cornea will very rarely be displaced onto the white part of the eye during wear. This, however, can occur if insertion and removal procedures are not performed properly. To center a lens, follow either of these procedures:

- a. Close your eyelids and gently massage the lens into place through the closed lids.

OR

- b. Gently manipulate the off-centered lens onto the cornea while the eye is opened, using finger pressure on the edge of the upper lid or lower lid.

6. Removing the Lens

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.

CAUTION: Always be sure the lens is on the cornea before attempting to remove it. Determine this by covering the other eye. If vision is blurred, the lens is either on the white part of the eye or it is not on the eye at all. To locate the lens, inspect the upper area of the eye by looking down into a mirror while pulling the upper lid up. Then inspect the lower area by pulling the lower lid down.

- b. There are two recommended methods of lens removal: the Pinch Method and the Forefinger and Thumb Method. You should follow the method that is recommended by your Eye Care Professional.

Pinch Method:

1. Look up, slide the lens to the lower part of the eye using the forefinger.
2. Gently pinch the lens between the thumb and forefinger.
3. Remove the lens.

Forefinger and Thumb Method:

1. Place your hand or towel under your eye to catch the lens.
2. Place your forefinger on the center of the upper lid and your thumb on the center of the lower lid.
3. Press in and force a blink. The lens should fall onto your hand or the towel.

4. Once the lens is removed, DISCARD the lens.

Note: The lens may come out, but remain on the eyelid, finger or thumb.

5. Remove and discard the other lens by following the same procedure.

Note: If these methods of removing your lens are difficult for you, your Eye Care Professional will provide you with an alternate method.

CARING FOR YOUR LENSES

Remember, there is no cleaning or disinfection needed with VISTAKON® (etafilcon A) Disposable Contact Lenses. Always dispose of lenses when they are removed and have replacement lenses or spectacles available.

Your Eye Care Professional may recommend a lubricating/rewetting solution for your use. **Lubricating/rewetting** solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

1. Care for a Sticking (non-moving) Lens

If a lens sticks (stops moving) on your eye, apply a few drops of the recommended lubricating solution.

You should wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, you should immediately consult your Eye Care Professional.

2. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (Monovision)

- You should be aware that as with any type of lens correction, there are advantages and compromises to presbyopic contact lens correction. The benefit of clear near vision in straight ahead and upward gaze that is available with VISTAKON® (etafilcon A) Contact Lenses for Monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to this. Symptoms, such as mild blurred vision and variable vision, may last for a brief period or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your chances for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually

demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with Monovision correction if you pass your state drivers license requirements with Monovision Correction.

- Some presbyopic patients require supplemental spectacles to wear over the VISTAKON® (etafilcon A) Contact Lenses for Monovision to provide the clearest vision for critical tasks. You should discuss this with your Eye Care Professional.
- Some presbyopic patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your Eye Care Professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- It is important that you follow your Eye Care Professional's suggestions for adaptation to presbyopic contact lens correction. You should discuss any concerns that you may have during and after the adaption period.
- The decision to be fit with Monovision correction is most appropriately left to the Eye Care Professional, in conjunction with you, after carefully considering and discussing your needs.

WEARING AND APPOINTMENT SCHEDULE

Prescribed Wearing Schedule

Day	Wearing Time (Hours)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	

Appointment Schedule

Your appointments are on:

Minimum number of hours lenses to be worn at time of appointment:

Month: _____ Year: _____

Time: _____ Day: _____

PATIENT/EYE CARE PROFESSIONAL INFORMATION

Next Appointment: _____

Date: _____

Dr.: _____

Address: _____

Phone: _____

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PROFESSIONAL IMMEDIATELY.

Day	Date	Hours worn
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Notes: _____



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

VISTAKON[®] is a registered trademark of Johnson & Johnson Vision Care, Inc.

© JJVCI 2001

Printed in U.S.A.

Revision date: 4/01

Revision number: AS-04-01-02