# PATIENT INSTRUCTION GUIDE

# 1-DAY ACUVUE® TruEye® Brand Contact Lenses with HYDRACLEAR® 1 Technology (narafilcon A)

Visibility Tinted with UV Blocker for Daily Wear Single Use Only

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# INTRODUCTION

The information and instructions contained in this booklet apply only to the 1-DAY ACUVUE® TruEye® Brand Contact Lenses with HYDRACLEAR® 1. Your contact lenses are intended to be used for daily wear single use only within the Johnson & Johnson Vision Care, Inc. planned lens replacement system.

Please refer to the Glossary of Technical Terms for definitions of medical/technical terminology used in this booklet. In addition, the Symbols Key provides an explanation of symbols that may appear on the lens packaging.

After the wearing period prescribed by your Eye Care Professional, your contact lenses should be discarded and replaced with a new sterile pair. If you have any questions, always ask your Eye Care Professional. By replacing your contact lenses on a regular basis, lens deposits, which can affect vision and cause irritation and discomfort to the eye, have little chance to build up over time as with conventional lens wear. When you discard the lens, you dispose of potential deposit build-up problems.

Your contact lenses are visibility tinted with a UV Blocker. An ultraviolet (UV) radiation absorbing ingredient is used to block UV radiation.

For your eye health, it is important that your contact lenses be worn only as prescribed by your Eye Care Professional. Your Eye Care Professional should be kept fully aware of your medical history and will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling and care, including how to safely and easily open the packaging. You will also be taught how to properly apply and remove lenses. This booklet will reinforce those instructions.

If you have any questions, always ask your Eye Care Professional.

# INDICATIONS (USES) AND WEARING RESTRICTIONS

All 1-DAY ACUVUE® TruEye® Brand Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The 1-DAY ACUVUE® TruEye® Brand Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have 1.00D or less of astigmatism.

Your Eye Care Professional should prescribe the lenses for daily wear single use only. The Eye Care Professional will determine your wearing schedule. Your lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

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

**DO NOT USE** your contact lenses when any of the following conditions exists:

- Inflammation or infection in or around the eve or evelids
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- · Any previously diagnosed condition that makes contact lens wear uncomfortable
- · Severe dry eye
- Reduced corneal sensitivity (corneal hypoesthesia)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- · If eyes become red or irritated

#### WARNINGS

#### What You Should Know About Contact Lens Wear:

- Problems with contact lenses or lens care products could result in serious injury to the eye¹.
   Proper use and care of your contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- Eye problems, including a sore or lesion on the cornea (corneal ulcers) can develop rapidly and lead to loss of vision.
- The risk of an infected sore or lesion on the cornea (ulcerative keratitis) is greater for people who
  wear extended wear contact lenses than for those who wear daily wear lenses.
- When daily wear users wear their lenses overnight (outside the approved use), the risk of an
  infected sore or lesion on the cornea (ulcerative keratitis) is greater than among those who do not
  wear them while sleeping.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- The risk of ulcerative keratitis among contact lens users who smoke is 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.

<sup>1</sup>New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

WARNING: UV ABSORBING CONTACT LENSES are not substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sun glasses 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.

## **PRECAUTIONS**

#### Handling Precautions:

- DO NOT use if the sterile blister package is opened or damaged.
- Before leaving the Eye Care Professional's office, you should be able to quickly remove your lenses or you should have someone else available who can remove the lenses for you.
- Always wash and rinse your hands before handling your 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 completely clean, because tiny lens scratches may occur, causing unclear vision and/or injury to your eye.
- Carefully follow the handling, insertion, removal and wearing instructions in this booklet and those prescribed by the Eye Care Professional.
- Always handle lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens and the packing solution into the hand.
- Do not touch the lens with your fingernails.

### **Lens Wearing Precautions:**

- You should remove your lenses immediately if your eyes become red or irritated.
- Never wear your lenses beyond the amount of time recommended by your Eye Care Professional.
- If aerosol (spray) products, such as hair spray, are used while wearing lenses, exercise caution and keep your eyes closed until the spray has settled.
- 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 germs.
- Always throw away lenses worn as prescribed by your Eye Care Professional.

#### Lens Care Precautions:

 The Eye Care Professional should review with the patient that no cleaning or disinfecting is needed with daily wear single use lenses. Patients should dispose of lenses when they are removed and have replacement lenses or spectacles available.

#### Other Topics to discuss with Your Eye Care Professional:

- If you wear your contact lenses to correct presbyopia using monovision you may not be able
  to get the best corrected visual acuity for either far or near vision. Visual needs are different for
  different people, so your Eye Care Professional should work with you when selecting the most
  appropriate type of lens for you.
- Always contact your Eye Care Professional before using any medicine in your eyes.
- Be aware that certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness may cause dryness of the eye, increased lens awareness (feeling of the lens in the eye) or blurred vision. Always inform your Eye Care Professional if you experience any problems with your lenses while taking such medications. Depending on the severity, your Eye Care Professional may prescribe the use of lubricating (wetting) drops that are indicated for use with soft contact lenses or may recommend that you stop wearing contact lenses while you are using these medications.
- Be aware that if you use oral contraceptives (birth control pills), you could develop changes in vision or comfort when wearing contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes.

# Who Should Know That You are Wearing Contact Lenses:

- Inform your doctor (Health Care Professional) about being a contact lens wearer.
- 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.

# ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

Be aware that the following problems may occur when wearing contact lenses:

- Your eyes may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on your eye.
- $\bullet$  There may be a feeling of something in your eye (foreign body, scratched area).
- There may be the potential for some temporary harm due to peripheral infiltrates, peripheral
  corneal ulcers and corneal erosion. There may be the potential for other physiological
  observations, such as local or generalized edema, corneal neovascularization, corneal staining,
  injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in
  low amounts.
- There may be excessive watering, unusual eye secretions or redness of your eye.
- Poor vision, blurred vision, rainbows or halos around objects, sensitivity to light (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?
- Have I noticed a change in my vision?

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 eve. You should discard the lens and insert a new fresh lens on your eve.

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. You should **immediately be seen by an Eye Care Professional** to identify the problem and get quick treatment to avoid serious eye damage.

#### PERSONAL CLEANLINESS FOR LENS HANDLING AND INSERTION

# 1. Prepare 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

Each multipack contains individually packaged lenses. Each lens comes in its own lens package designed specifically to keep it sterile. You may choose to keep your lenses inside the multipack for storage until you are ready to use them.

#### Lens Package

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

- a. Shake the lens package and check to see that the lens is floating in the solution.
- b. Peel back the foil closure to reveal the lens. By stabilizing the lens package on the table-top, you will minimize the possibility of a sudden splash.
- c. 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

Occasionally, a lens may stick to the inside surface of the foil when opened, or to the plastic package itself.

# 3. Handling the Lenses

- When you first get your lenses, be sure that you are able to put the lenses on and remove them before leaving your Eye Care Professional's office.
- 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.

# 4. Placing the Lens on the Eye

### Remember, always start with the same eye.

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

- 1. BE SURE THE LENS IS NOT INSIDE-OUT by following either of the following procedures:
  - Place the lens on the tip of your index finger and check 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.

#### OR

- Place the lens on the tip of your index finger and, looking up at the lens, locate the numbers 123.
   1-2-3 indicates correct orientation while a reverse of 1-2-3 indicates the lens is inside out. If the lens is inside out (reverse 1-2-3), invert the lens and locate the numbers again to confirm correct lens orientation.
- 2. Place the middle finger of the same hand close to your lower eyelashes and pull down the lower lid.
- 3. Use the index finger or middle finger of the other hand to lift the upper lid.
- 4. Place the lens on the eye.
- 5. Gently release the lids and blink. The lens will center automatically.
- 6. Use the same technique when inserting the lens for your other 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.

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

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

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.

If your examination of your eyes and the lenses shows any other problems, IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYE CARE PROFESSIONAL.

#### 5. Centering the Lens

A lens, which is on the cornea (center of your eye), will very rarely move 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 move the off-centered lens onto the cornea (center of your eye) while the eye is opened using finger pressure on the edge of the upper lid or lower lid.

# 6. Removing the Lens

**CAUTION:** Always be sure the lens is on the cornea (in the center of your eye) 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.

Always remove the same lens first.

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

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

#### Forefinger and Thumb Method:

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

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

- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care procedures described under the heading, "Caring For Your Lenses (Cleaning, Rinsing, Disinfecting, Storage and Rewetting/Lubricating)".

**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

#### 1. Basic Lens Care Instructions

If you require only vision correction, but will not or cannot always use the recommended care routine for your lenses, or are unable to put on and remove lenses or have someone available to place and remove them, you should not try to get and wear contact lenses.

- When you first get your lenses, be sure to put the lenses on and remove them while you
  are in your Eye Care Professional's office.
- Always wash, rinse and dry your hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:
  - a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
- b. You might lose your lens down the drain.

# 2. For Daily Wear Single Use:

Remember, there is no cleaning or disinfection needed with 1-DAY ACUVUE® TruEye® Brand Contact Lenses prescribed for daily wear single use only. Always dispose of lenses when they are removed and have replacement lenses or spectacles available.

# 3. 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.

#### 4. Care For A Dried Out (Dehydrated) Lens

If a soft contact lens is exposed to air for prolonged periods while off the eye, it may become dry and can be easily broken. If this happens, throw away the lens and use a new fresh one.

#### 5. 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 when looking straight-ahead and upward that you get with your contact lenses for monovision correction 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 you are getting used to the lenses. The longer these symptoms last, 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 that are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first 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 need to wear their glasses over their contact lenses for monovision correction 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 lighting, 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 from both eyes together.

For monovision patients, if you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near vision is required from both eyes together. It is important that you follow your Eye Care Professional's suggestions for getting used to presbyopic contact lens correction. You should discuss any concerns that you may have during and after the adaptation 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.

GLOSSARY OF TECHNICAL TERMS		
Term	Definition	
Adnexa	Tissues surrounding the eyeball	
Ametropia	Abnormal vision requiring correction for proper focus	
Anterior chamber	Internal portion of the eye, between the cornea and iris	
Aphakic	An eye that does not have its natural lens (example: after cataract surgery)	
Aspherical contact lens	A lens with a curve that is not round, but has different shapes across its surface	
Astigmatism	A condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape, causing the visual image to be out of focus (blurred)	
Conjunctiva	Membrane that lines the eyelids and the white part of the eye	
Conjunctivitis	Inflammation of the conjunctiva	
Continuous Wear	Continuous Wear Extended wear for multiple nights in a row	
Cornea	Clear front part of the eye that covers the iris, pupil and anterior chamber	
Corneal erosion	Wearing away of the surface of the cornea	
Corneal staining	When a dye is put onto the eye and shows problems with the corneal surface	
Corneal ulcer	A sore or lesion on the comea	
Disinfection	A process that kills harmful microorganisms (germs) which can cause serious eye infections	
Edema	Swelling of tissue from excess fluid accumulation	
Extended Wear	Wearing lenses for 24 hours a day, including while sleeping	
Hydrophilic material	"water loving" or water absorbing substance	
Hyperopia	Farsightedness	
Infiltrate	Abnormal accumulation of cells and fluid	
Injection	Redness	
Iritis	Inflammation of the colored part of the eye (iris)	
Inflammation	Swelling, redness and pain	
Monovision	A correction method for presbyopia (loss of reading vision) using contact lenses; one eye is fitted for distance, the other for near vision.	
Multifocal contact lens	A lens that can correct for both distance and near vision	
Муоріа	Nearsightedness	
Neovascularization	Blood vessels growing into the cornea	
Phakic	An eye that has its natural lens	
Presbyopia	Condition in which as the lenses in the eyes lose some of their elasticity, as occurs with aging, they lose some of their ability to change focus for different distances (loss of reading vision). Usually becomes significant after age 45.	
Spherical contact lens	A lens with a continuously rounded curve	
Tarsal abnormalities	Problems with the eyelids	
Toric contact lens	A lens with two different optical powers at right angles to each other for the correction of astigmatism	
Ulcerative keratitis	An infected corneal ulcer	
UV (Ultraviolet)	Light from the sun that can be harmful to the eye	

# SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION
<u> </u>	See Instruction Leaflet
$\square$	Use By Date (expiration date)
LOT	Batch Code
STERILE	Sterile Using Steam or Dry Heat
DIA	Diameter
ВС	Base Curve
D	Diopter (lens power)
<b>C€</b> 0086	Quality System Certification Symbol
UV BLOCKING	UV-Blocking
<b>O</b>	Fee Paid for Waste Management
#	Peel Back Foil
<b>R</b> Only	CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner
C.T.	Center Thickness
0.K.	<b>Lens Orientation Correct</b>
X	Lens Inside Out
[]i	Consult Instructions for Use
	Manufactured by or in

# 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		
Appointr	ntment Schedule	
Your appoir	ointments are on:	
Minimum n	number of hours lenses to be worn at time of appointment:	
Month:	Year:	
Time:	Day:	

#### PATIENT / EYECARE PROFESSIONAL INFORMATION

Next App	ointment:					
Date:						
Dr:						
Address:						
Phone:						
Day	Date	Hours Worn	Day	Date	Hours Worn	
1			1			
2			2			
3			3			
4			4			
5			5			
6			6			
7			7			

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.

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