

Signature Page for LB20211DAVD4093 v1.0

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define[®] 1-DAY ACUVUE[®] with LACREON[®]

(etafilcon A) Soft (hydrophilic) Contact Lenses
Cosmetically Tinted with UV Blocker
for Daily Disposable Wear

PATIENT INSTRUCTION GUIDE



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

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INTRODUCTION

About This Booklet:

The information and instructions contained in this booklet apply only to 1-DAY ACUVUE® DEFINE® Brand Contact Lenses with LACREON® Technology.

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 develop 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 insert and remove lenses. This booklet will reinforce those instructions.

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

A “Glossary of Commonly Used Terms” is included for your reference. This contains definitions of medical and technical terminology used in this booklet. In addition, a “Symbols Key” provides an explanation of symbols that may appear on the lens packaging.

Special sections are included in the back of this booklet to record your specific prescribed wearing information, as well as to record the contact information for your Eye Care Professional.

About Your Lenses and Contact Lens Wear:

Your contact lenses are made from a water loving (hydrophilic) material that has the ability to absorb water, making the lenses soft and flexible. The lenses are tinted to improve visibility for handling and also contain an ultraviolet (UV) radiation absorbing ingredient to block UV radiation.

1-DAY ACUVUE® DEFINE® Brand Contact Lenses are intended to enhance or alter the appearance of your natural eye. These lenses are also intended for the correction of nearsightedness (myopia) and farsightedness (hyperopia).

These lenses are available in the following patterns/styles:

- ACCENT STYLE
- VIVID STYLE
- RADIANT SHINE

When prescribed for daily disposable wear, lenses should be discarded upon removal, and therefore no cleaning or disinfection is required. You should always have spare lenses or glasses available.

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.

Clinical research has shown that when worn on a daily disposable basis, these lenses may provide improved comfort for 2 out of 3 patients who reported suffering from discomfort associated with allergies during contact lens wear.

SYMBOLS KEY

The following symbols may appear on the label or carton:

<i>Symbol</i>	<i>Description</i>
	Caution, Consult Instructions for Use
	Date of Manufacture
	Manufacturer
	Use By Date (expiration date)
	Batch Code
	Sterilized Using Steam Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
	CE-mark and Identification Number of Notified Body
	UV-Blocking
	Fee Paid for Waste Management
	CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Do Not Re-Use (Single Use)
	Do Not Use if Package is Damaged and Consult Instructions for Use
	Medical Device in the European Community
	Indicates a Single Sterile Barrier System
	Authorized Representative in the European Community
	Contains Hazardous Substances
UV BLOCKING	UV Blocking
	Lens Orientation Correct
	Lens Orientation Incorrect(Lens Inside Out)

	Package Opening Icon (Blister)
	Package Opening Icon (Carton)

GLOSSARY OF COMMONLY USED TERMS

<i>Term</i>	<i>Definition</i>
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).
Conjunctivitis	Inflammation of the membrane that lines the eyelids and the white part of the eye
Cornea	Clear center part of the eye
Corneal Ulcer	A sore or lesion on the cornea
Inflammation	Swelling, redness, and pain

WEARING RESTRICTIONS & INDICATIONS

1-DAY ACUVUE® DEFINE® Brand Contact Lenses are intended to enhance or alter the appearance of your natural eye. These lenses are also intended for the correction of nearsightedness (myopia) and farsightedness (hyperopia) in people with non-diseased eyes who may have 1.00D or less of astigmatism.

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

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

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

Your Eye Care Professional will determine your wearing schedule (how long you should wear your lenses each day). When prescribed for daily disposable wear, lenses should be discarded upon removal.

WHEN LENSES SHOULD NOT BE WORN (CONTRAINDICATIONS)

There are certain health conditions with which contact lenses should not be worn. You should alert your Eye Care Professional to any of the conditions listed below. Only your Eye Care Professional can determine if contact lens wear is right for you.

- Inflammation or infection in or around the eye or eyelids
- 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
- Any systemic disease that may affect the eye or may be made worse by wearing contact lenses
- Allergic reactions on the surface of the eye or surrounding tissues that may be induced or made worse by wearing contact lenses
- Irritation of the eye caused by allergic reactions to ingredients in contact lens solutions (i.e., rewetting drops). These solutions may contain chemicals or preservatives (such as mercury, Thimerosal, etc.) to which some people may develop an allergic response
- Any active eye infection
- If eyes become red or irritated

WARNINGS

What You Should Know About Contact Lens Wear:

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. IF YOU EXPERIENCE:

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes,**
- **Loss of Vision,**
- **Eye Redness, or**
- **Other Eye Problems,**

YOU SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PROFESSIONAL.

- When prescribed by your Eye Care Professional for daily disposable wear (i.e., your Eye Care Professional instructs you to remove and discard your lenses at the end of each day), you should not wear your lenses while sleeping. Clinical studies have shown that the risk of serious eye problems is increased when lenses are worn overnight.¹
- Studies have shown that contact lens wearers who smoke have a higher rate of eye problems than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye.
- Proper use and care of your contact lenses and lens care products are essential for the safe use of these products.
- The overall risk of serious eye problems may be reduced by carefully following directions for lens care.

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

Specific Instructions for Use and Warnings:

- **Water Activity**

Instruction for Use

Do not expose your contact lenses to water while you are wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water when participating in water sports or swimming in pools, hot tubs, lakes, or oceans, you should discard them and replace them with a new pair. Ask your Eye Care Professional for recommendations about wearing your lenses during any activity involving water.

PRECAUTIONS

For your eye health, it is important to carefully follow the handling, insertion, removal, and wearing instructions in this booklet, as well as those prescribed by your Eye Care Professional (see “**Lens Handling & Insertion**” and “**Lens Wearing**” sections).

General Precautions:

- 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 your symptoms, your Eye Care Professional may recommend rewetting drops that are available 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. Ask your Eye Care Professional about the recommended follow-up schedule.

Who Should Know That You are Wearing Contact Lenses:

- **Inform** all of your doctors (Health Care Professionals) 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 (POSSIBLE PROBLEMS WITH LENS WEAR)

Possible Problems

Be aware that problems can occur while wearing contact lenses and may or may not be associated with the following symptoms:

- burning, stinging and/or itchy eyes
- reduced lens comfort
- feeling of something in your eye (foreign body, scratched area)
- swelling or inflammation in or around the eyes
- eye redness
- eyelid problems
- watery eyes
- unusual eye secretions
- poor vision
- blurred vision
- rainbows or halos around objects
- sensitivity to light (photophobia)
- dry eyes

When any of the above symptoms occur, a serious eye condition may be present. You should **immediately be seen by your Eye Care Professional**, so that the problem can be identified and treated, if necessary, in order to avoid serious eye damage.

Recognizing Problems and What To Do

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 notice any problems, you should IMMEDIATELY REMOVE YOUR LENS. If the problem or discomfort stops, discard the lens and place a new fresh lens on the eye.

If after inserting the new lens, the problem continues, IMMEDIATELY REMOVE THE LENS AND CONTACT YOUR EYE CARE PROFESSIONAL.

Do NOT use a new lens as self-treatment for the problem.

LENS HANDLING AND INSERTION

For your eye health, it is important to carefully follow the handling, insertion, removal, and wearing instructions in this booklet as well as those prescribed by your Eye Care Professional. If you will not or cannot always follow the recommended care procedures, you should not attempt to wear contact lenses.

When you first get your lenses, be sure that you are able to put the lenses on and remove them (or have someone else available who can remove the lenses for you) before leaving your Eye Care Professional's office.

Step 1: Getting Started

It is essential that you learn and use good hygiene 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, dry, and free of any soaps, lotions, or creams before you handle your lenses.

Before you start:

- Always wash your hands thoroughly with a mild soap, rinse completely and dry with a lint-free towel before touching your lenses.

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.

- You should avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses. These substances may come into contact with the lenses and interfere with successful wearing.

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.

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

Step 2: Opening the Packaging

Multipack

Each multi-pack contains individually packaged lenses. Each lens comes in its own foil-sealed plastic package containing borate buffered saline solution with povidone. This package is designed specifically to keep the lens sterile while the package is sealed. In the European Union, Borates (boric acid & sodium borate) are defined as CMR 1B substances in a concentration above 0.1% weight by weight and are safe when product is used according to label instructions.

Lens Package

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

DO NOT use if the sterile blister package is opened or damaged.

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 table-top, you will minimize the possibility of a sudden splash.
3. 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.

NEVER use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use.

Occasionally, a lens may stick 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.

Lens Handling Tips

- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

DO NOT touch the lens with your fingernails.

- Develop the habit of always working with the same lens first to avoid mix-ups.
- After you have removed the lens from the packaging, examine it to be sure that it is moist, clean, and free of any nicks or tears. If the lens appears damaged, DO NOT use it. Use the next lens in the multipack.

ALWAYS handle lenses carefully and avoid dropping them.

Step 3: 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 insert the lens into 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.
2. With the lens on your index finger, use your other hand to hold your upper eyelid so you won't blink.
3. Pull down your lower eyelid with the other fingers of your "inserting" hand.
4. Look up at the ceiling and gently place the lens on the lower part of your eye.
5. Slowly release your eyelid and close your eye for a moment.
6. Blink several times to center the lens.
7. 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, ask your Eye Care Professional for an alternate method.

Step 4: Checking Your Lenses

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?

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

- The lens is not centered on the eye (see “*Step 5: Centering the Lens,*” next in this booklet).
- If the lens is centered, remove the lens (see “*Removing Your Lenses*”) and check for the following:
 - Cosmetics or oils on the lens. Dispose of the lens and insert a new fresh lens.
 - The lens is on the wrong eye.
 - The lens is inside out (it would also not be as comfortable as normal). See “*Step 3: Placing the Lens on the Eye.*”

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

Note: If a lens is noticeably uncomfortable upon insertion or becomes less comfortable than when it was first inserted, 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.

Step 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:

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

OR

- 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.

LENS WEARING

While wearing your lenses, remember the following important precautions:

Cosmetic Lenses and Visual Symptoms

- Cosmetically tinted contact lenses may let less light through than non-cosmetic lenses. Therefore, you may experience some visual symptoms while wearing them (i.e., seeing the lens pattern in your peripheral vision).

Hazardous Conditions

- If you use aerosol (spray) products, such as hair spray, while wearing lenses, keep your eyes closed until the spray has settled.
- **Avoid** all harmful or irritating vapors and fumes while wearing lenses.

Water Activity

- Do not expose your contact lenses to water while you are wearing them.

Lubricating/Rewetting Solutions

- Your Eye Care Professional may recommend a lubricating/rewetting solution for your use. These solutions can be used to wet (lubricate) your lenses while you are wearing them.
- **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:
 1. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 2. You might lose your lens down the drain.

Sticking (Non-Moving) Lens

- For your eye health, it is important that the lens moves freely on your eye.
- If the lens sticks (stops moving) on your eye, apply a few drops of the recommended rewetting solution. 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.

Sharing Lenses

- **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 increases the chance of eye infections.

Adhering to the Prescribed Wearing & Replacement Schedules

- **Never** wear your lenses beyond the amount of time recommended by your Eye Care Professional.
- **Always throw away** worn lenses as prescribed by your Eye Care Professional.

REMOVING YOUR LENSES

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.

1. Wash, rinse, and dry your hands thoroughly.
2. 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 forefinger 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.

3. Remove the other lens by following the same procedure.

Remember, there is no cleaning or disinfection needed with your contact lenses when they are prescribed for daily disposable wear. Always dispose of lenses when they are removed and have replacement lenses or glasses available.

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

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 RIGHT AWAY.**

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (MONOVISION)

About Presbyopia and Monovision Correction

- Presbyopia is a condition in which the natural lenses in the eyes lose some of their elasticity. This occurs normally with aging as the lenses lose some of their ability to change focus for different distances (loss of reading vision).
- Monovision is a method of correction for presbyopia using contact lenses in which one eye is corrected for distance vision and the other is corrected for near vision.

Getting Used to Monovision Correction (Adaptation)

- Be aware that, as with any type of lens correction, there are advantages and compromises to monovision contact lens correction. The benefit of clear near vision when looking straight-ahead and upward that you get with your contact lenses for monovision may be accompanied by a vision compromise that may reduce the sharpness of your vision and depth perception for distance and near tasks. Some people have experienced difficulty adapting to this. You may experience symptoms, such as mild blurred vision and variable vision during this adaptation period. These symptoms 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 may be 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 a car during the first days of lens wear. Also, it is recommended that you only drive with monovision correction if you pass your state driver's license requirements with monovision correction.
- It is important that you follow your Eye Care Professional's suggestions for getting used to monovision contact lens correction. You should discuss any concerns that you may have during and after the adaptation period.

Additional Correction Needs

- Some patients with monovision correction will need to wear their glasses over their contact lenses to provide the clearest vision for critical tasks. You should discuss this with your Eye Care Professional.
- Some 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 about having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required from both eyes together.
- 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.

The decision to be fit with monovision correction is most appropriately left to your 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: _____

Day	Date	Hours Worn	Day	Date	Hours Worn
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		
7			7		

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

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