

PATIENT INSTRUCTION / WEARER'S GUIDE

For the

***PolyVue High Definition™ (polymacon)
Soft Hydrophilic Contact Lens for Daily Wear
(clear and tinted, fully cast-molded lens)***

***CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON
THE ORDER OF A LICENSED PRACTITIONER.***

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CONGRATULATIONS:

You have just received your new ***PolyVue High Definition™ Soft Contact Lens***. ***PolyVue High Definition™*** lenses are available as ***Aspherical (HD)***, ***Toric (HD-T)***, ***Multifocal (HDX)***, and ***Toric Multifocal (HDX-T)*** contact lenses. This booklet has been prepared to help you care for it. Please read it carefully and follow the instructions so that you receive full satisfaction from your lens.

PRACTITIONER:

ADDRESS:

TELEPHONE:

Daily Cleaner:

Rinsing Solution:

Disinfecting Solution:

Lubricant/Rewetting Drops:

Enzymatic Cleaner:

Rewetting Solution:

INTRODUCTION:

With your decision to wear soft (hydrophilic) contact lens, you have joined a growing number of people who are discovering new pleasures from this important advance in vision correction.

Your ***PolyVue High Definition™ Contact Lens*** is made of a stable, inert, highly purified, hydrophilic (water absorbing) polymer with properties different from conventional rigid lens. Fully cast-molded to optical precision in the dry state, your lens hold these qualities in the soft, moist state in which they are suited for your use. Kept moist by the tears in your eyes, the lens is soft and comfort can be immediate. You are cautioned, however, to follow the initial wearing time schedule prescribed by your practitioner and not to overwear the lens simply because they remain comfortable. Your eyecare practitioner will determine your appropriate wearing schedule.

Although soft and pliable, your lens is strong and durable. The life of your ***PolyVue High Definition™ Contact Lens*** will depend to a large extent on how you handle and care for them. As with all precision devices, proper use will assure you the benefits of convenience, comfort, and confidence in your lens.

Read this Wearer's Guide carefully. It contains the information you need to know to wear, handle, and care for your ***PolyVue High Definition™ Contact Lens***. If you are in doubt about any instructions, request clarification from your eyecare practitioner.

WEARING RESTRICTIONS and INDICATIONS:

The ***PolyVue High Definition***[™] (polymacon) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or visibility tinted.

Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

The ***PolyVue High Definition***[™] Contact Lens described in this booklet should be removed from your eyes for routine cleaning and disinfecting daily as prescribed by your eyecare practitioner.

DO NOT WEAR YOUR *PolyVue High Definition*[™] DAILY WEAR CONTACT LENS WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the *PolyVue High Definition*[™] Contact Lens when any of the following conditions exist:

- Acute and 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).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the ***PolyVue High Definition***[™] (polymacon) Soft Contact Lens.
- Any active corneal infection (bacterial, fungi, or viral)
- If eyes become red or irritated.
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS:

- **PROBLEMS WITH CONTACT LENS AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that you follow your eyecare practitioner's direction and all labeling instructions for proper use of lens and lens care products, including the lens case. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENS AND PROMPTLY CONTACT YOUR EYECARE PRACTITIONER.**

- Daily wear lens are not indicated for overnight wear, and you are instructed not to

wear the ***PolyVue High Definition***[™] Contact Lens while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lens are worn overnight.

- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers do.

PRECAUTIONS:

- * Different solutions cannot always be used together, and not all solutions are safe for use with all lens. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lens 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, STERILE UNEXPIRED lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. 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 solution for lubricating or rewetting lens. Always keep the lens completely immersed in the recommended storage solution when the lens is not being worn (stored). Prolonged periods of drying will damage the lens. Follow the lens care directions for care for a dried out (dehydrated) dry lens if the lens surface does become dried out.
- * If the lens sticks (stops moving) on the eye, follow the recommended directions on care for sticking lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to IMMEDIATELY consult his or her eyecare practitioner.
- * Always wash and rinse hands before handling lens. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on lens before putting on makeup. Water-base cosmetics are less likely to damage lens than oil-base.
- * Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- * Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the patient instructions for the ***PolyVue High Definition***[™] Contact Lens and those prescribed by the eyecare practitioner.
- * Never wear lens beyond the period recommended by the eyecare practitioner.
- * If aerosol products such as hair spray are used while wearing lens, exercise caution and keep eyes closed until the spray has settled.
- * Always handle lens carefully and avoid dropping them.
- * Avoid all harmful or irritating vapors and fumes while wearing lens.
- * Ask the eyecare practitioner about wearing lens during sporting activities.
- * Inform the doctor (health care practitioner) about being a contact lens wearer.
- * Never use tweezers or other tools to remove lens from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- * Do not touch the lens with fingernails.
- * Always contact the eyecare practitioner before using any medicine or medications 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 lens.
- * 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.
 - * Always discard lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eyecare practitioner.

ADVERSE REACTIONS:

The following problems may occur:

- * Eyes stinging, burning, itching (irritation), or other eye pain.
- * Comfort is less than when lens was first placed on eye.
- * Feeling that something is in the eye such as a foreign body or scratched area.
- * Excessive watering (tearing) of the eye.
- * Unusual eye secretions.
- * Redness of the eye.
- * Reduced sharpness of vision (poor visual acuity).
- * Blurred vision, rainbows, or halos around objects.
- * Sensitivity to light (photophobia).
- * Dry eyes.

If you notice any of the above, IMMEDIATELY REMOVE YOUR LENS.

- * If discomfort or problems stops, then look closely at the lens. If the lens is in way damaged, DO NOT PUT THE LENS BACK ON YOUR EYE. Place the lens in the storage case and contact your eyecare practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lens, then reinsert them. After reinsertion, if the problem continues, you should IMMEDIATELY REMOVE THE LENS AND CONSULT YOUR EYECARE PRACTITIONER.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS and LENS HANDLING

Before Handling Your Lens:

Cleanliness is an important aspect of contact lens care.

Before handling your lens, always wash and rinse your hands thoroughly and dry them with a lint-free towel. Do not use soaps, lotions, cold creams, or perfumes which leave a residue on your hands. Avoid using medications, creams, deodorants, make-up, after shave lotions, or similar items prior to touching your lens. When hair spray is used, the eye must be kept closed until the spray has settled. Take care in handling your lens. Always avoid touching your lens with your fingernails or other sharp objects. NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.

Handling and Placing the Lens on the Eye:

- 1) To avoid the possibility of lens mix-ups, always start with the same lens first.
- 2) Before inserting the lens, rinse well with fresh, sterile rinsing solution. Then place the lens on the tip of the index finger of your dominant hand.
- 3) While positioned on your index finger, check to ensure the lens has not turned inside out. To check this, look at the profile of the lens against a light background. If the edge profile appears convex and bowl-shaped, then it is correct. If the lens is inverted, it will flare out at the edge. If the lens is inverted, simply reverse it by using light fingertip pressure. Be sure to avoid damaging the lens with your fingernails.
- 4) Look straight ahead and raise the upper lid with your other index finger.
- 5) Then look down, keep both eyes open and place the lens on the upper white part of the eye.
- 6) Slowly release upper lid, and gently close your eye.
- 7) The lens should center automatically, or it can be moved on center by gentle fingertip pressure through the lids.
- 8) Repeat the above procedure for the second lens.
- 9) If the lens appears to be stuck on your eye, apply a few drops of a recommended lubricating or rewetting solution to the eye and blink a few times. If the lens does not move freely on your eye, contact your eyecare practitioner for further instructions.

There is no single "right way" of putting on lens. If you find this method of lens placement difficult, your eyecare practitioner will suggest another method or provide additional information.

Removing the Lens:

Preparation:

- 1) Wash and rinse your hands thoroughly.
- 2) Dry hands with a lint-free towel.
- 3) Check that the lens is centered on the cornea before attempting to remove the lens. Check your vision by covering one eye. If vision is blurry, the lens is off-center. Re-center the lens before attempting to remove it.

Removal:

- 1) To avoid the possibility of lens mix-ups, always begin with the same lens.
- 2) Look up and keep both eyes open.
- 3) Using the middle finger of your dominant hand, gently pull down the lower lid of the first eye. Using the tip of your index finger of the same hand, touch the lens and slide it onto the white of the eye.
- 4) Gently "pinch" the lens between the index finger and the thumb and remove.
- 5) Repeat the procedure for the second eye.
- 6) If the lens cannot be easily moved, apply a few drops of lubricating or rewetting solution to the eye, blink a few times, and when the lens moves freely on the eye, remove in the manner described above. If the lens still cannot be moved, contact your eyecare practitioner for further instruction.
- 7) Upon removal, clean each lens with a contact lens cleaner per the procedures described under the heading, CARING FOR YOUR LENS. Rinse well with rinsing solution and place in the lens storage case filled with fresh storage solution.

IMPORTANT: Always avoid touching your lens with your fingernails. Use only your fingertips.

If you find this method difficult, your eyecare practitioner will suggest another method or provide additional instruction.

If the lens is chipped or torn, do not put the lens back on your eye. Return the lens to the storage case with fresh solution and contact your eyecare practitioner.

CARING FOR YOUR LENS

Basic Instructions:

For continued safe and comfortable wearing of your lens, it is important that you first clean and rinse, then disinfect your lens after each removal, using the care regimen recommended by your eyecare practitioner. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits, which may have accumulated after removing them. Disinfecting is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the warning section above.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lens, or are unable to place and remove your lens or have someone available to place and remove them, you should not attempt to get and wear contact lens.

When you first get your lens, be sure you have to put the lens on and remove them while you are in your eyecare practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Wearer's Guide for the ***PolyVue High Definition***TM Contact Lens.

For safe contact lens wear, you should know and always practice your lens care routine:

- * Always wash, rinse, and dry hands before handling contact lens.
- * Always use fresh, sterile unexpired lens care solutions.
- * Use recommended system of lens care and carefully follow instructions on solution labeling.
- * Different solutions cannot always be used together, and not all solutions are safe for use with all lens. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.**
- * Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lens. Do not put lens in the mouth.
- * Never rinse your lens in water from the tap. There are two reasons for this:
 - a. Tap water contains many impurities that can contaminate or damage your lens and may lead to eye infection or injury.
 - b. You might lose the lens down the drain.
- * The eyecare practitioner should recommend a care system that is appropriate for the ***PolyVue High Definition***TM Contact Lens. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

- * Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- * After cleaning, disinfect lens using the system recommended by the manufacture and/or your eyecare practitioner.
- * To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lens are not to be used immediately following disinfection, you should consult the package insert or your eyecare practitioner for information on storage of lens.
- * Always keep your lens completely immersed in a recommended disinfecting solution when the lens is not being worn. If you discontinue wearing your lens, but plan to begin wearing them after a few weeks, ask your eyecare practitioner for a recommendation on how to store your lens.
- * ***PolyVue High Definition™*** Contact Lens can be disinfected using a chemical or heat disinfecting system.
- * Contact lens cases can be a source of bacteria growth. After removing the lens from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacture; 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 manufacture or your eyecare practitioner.
- * Your eyecare practitioner may recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to wet (lubricate) your lens while you are wearing them to make them more comfortable.
- * ***Lenses prescribed for planned (frequent) replacement:***
The ***PolyVue High Definition™*** Contact Lens may be prescribed in a planned (frequent) replacement program and should be thrown away after the recommended wearing period prescribed by the eyecare practitioner.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANER:

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lens and eyes. If these deposits are not removed, they can damage the lens and cause irritation. Enzyme cleaning does NOT replace routine cleaning and disinfecting.

For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

Lens Case Cleaning and Maintenance:

Contact lens cases can be a source of bacteria growth. After removing the lens from the 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 manufacture or your eyecare practitioner.

Care for a Sticking (non-moving) Lens:

If the lens sticks (cannot be removed), you should apply 3 to 4 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 15 minutes, you should IMMEDIATELY consult your eyecare practitioner.

Care for a Dried out (dehydrated) dry Lens:

If for some reason your lens dry out completely: a minimum of handling is important as they are very brittle in the dehydrated state. Carefully place them in rinsing or storage solution for a minimum of thirty minutes during which time they will become soft and flexible. Then follow the cleaning, rinsing, and disinfecting procedures, including soaking the lens in storage and disinfection solution for four hours before wearing again.

Chemical Disinfection:

1. Wash and rinse your hands thoroughly BEFORE HANDLING LENS.
2. After removal of lens, CLEAN the lens by applying three drops of cleaner to each surface. Then rub the lens between your fingers for 20 seconds.
3. AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
4. The lens should then be placed in a lens case and filled with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfecting, the lens must remain in the disinfecting solution for the recommended period of time as written on the solution bottle.

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 rinsing solution prior to placement on the eye should reduce the potential for irritation.

EMERGENCIES:

If any chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you should:

FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WHEN TO CALL YOUR PRACTITIONER?

Certain symptoms may be early indicators of potentially serious problems. A careful examination of your lens, and professional examination of your eyes, may be required. Remove the lens following the instructions outlined in this guide, and call your eyecare practitioner if:

- 1) Your eye becomes red and feels irritated or "gritty".
- 2) You notice a change in your vision or see rainbows or halos around objects.
- 3) You experience discomfort and/or sensitivity to lights.

A good general policy is:

"IF IN DOUBT ... TAKE THE LENS OUT" and contact your eyecare practitioner.

Learn and Use Proper lens Care Habits:

- 1) Follow Instructions.
- 2) Handle Lens Properly.
- 3) Learn How to Put On and Take Off Your Lens.
- 4) Keep Your Lens Clean.
- 5) Disinfection is a Necessary Security.

INSTRUCTIONS FOR MONOVISION WEARER

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that available with 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 it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis 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 you state drivers license requirements with monovision correction.
- Some monovision 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 eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

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 binocular vision is required.

- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.
- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. 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 eyecare practitioner in conjunction with you, after carefully considering and discussing your needs.

RECOMMENDED LENS CARE PRODUCTS

The eyecare practitioner should recommend a care system that is appropriate for the ***PolyVue High Definition™*** Contact Lens. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. The table below shows solutions that are recommended for use with the ***PolyVue High Definition™*** Contact Lens.

<i>Daily Cleaner:</i>	• Alcon Opti-Free Daily Cleaner
<i>Rinsing Solution:</i>	• Alcon Saline for Sensitive Eyes, • Alcon Unisol
<i>Disinfecting Solution:</i>	• Alcon Opti-Free (Rinsing, Disinfecting and Storage Solution). • Alcon Opti-One (Multi-Purpose Solution)
<i>Lubricant/Rewetting Drops:</i>	• Alcon Opti-Free Rewetting Drops
<i>Enzymatic Cleaner:</i>	• Alcon Optizyme Enzymatic Cleaner

WEARING SCHEDULE:

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY YOUR EYECARE PRACTITIONER.

The ***PolyVue High Definition™*** Contact Lens are indicated for daily wear. The maximum suggested wearing time for these lens is:

DAY	HOURS
1	6
2	8
3	10
4	12
5	14
6	All Waking hours *

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE “POLYVUE HIGH DEFINITION™ CONTACT LENS” IS SAFE TO WEAR DURING SLEEP.

APPOINTMENT SCHEDULE:

Your appointments are on:

Date:

Time:

IMPORTANT:

In the event that you experience any difficulty wearing your lens or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYECARE PRACTITIONER IMMEDIATELY.

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l. How Supplied (final packaging of product)

Each lens is supplied sterile in a sealed glass vial containing buffered normal saline solution. The glass vial label is marked with the base curve, diameter, dioptric power, add power, manufacturing lot number, and expiration date of the lens.

NOTE: Reference FDA approvals; 510(k) K020608 and K013220 for additional information regarding how the contact lenses are supplied to the licensed practitioner.

The ***PolyVue High Definition***TM final packaging label is as follows and is in draft form.

EXAMPLE:

