

HDS HI 1.54™ (pahrifocon A)

Rigid Gas Permeable Contact Lenses for Daily Wear

Instructions For Wearers



Just watch us®

Patient Name: _____

Date Dispensed: _____

Dispensed Lens

Lens Type

Daily Wear (DO NOT sleep in these lenses.)

Design

Aspheric

Toric

Bifocal

Other

Spherical

Material

HDS HI 1.54™

Lens Prescription

Eye	Base Curve	Power	Diameter	Color	Lot Number
Right					
Left					

Prescribed By

Dr. _____

Address: _____

Phone: _____

My cleaning and disinfecting system is: _____

Your HDS HI 1.54™ rigid gas permeable contact lens may be tinted blue or green as a handling aid for locating the lens. These products may be plasma treated.

CAUTIONS: Federal (US) law restricts this device to sale by, or on the order of a licensed practitioner. Nonsterile. Clean and condition prior to use.

NOTE: See the Package Insert for additional safety information.

WARNING: The practitioner should provide this warning to the patient.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your contact lenses and lens care products, including the lens case.

Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. They should discard their solution immediately after their lenses have been removed from the lens case. They should not store their lenses in or rinse their lens case with tap water, bottled water or any non-sterile solution.

Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner.

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, OR OTHER PROBLEMS WITH YOUR EYES, IMMEDIATELY REMOVE YOUR LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

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INTRODUCTION

Your eyes need oxygen to stay healthy and to keep you seeing well and feeling well. But, unlike all the other organs of your body, your eyes do not rely on the blood for oxygen. Instead they receive oxygen directly for the air and from the tears that continually bathe them. That's why it is important that today's contact lenses allow oxygen to pass through them so that the oxygen in the air can reach the eye's tissues. Just as importantly, contact lenses must be fitted properly by an eye care professional so that they will allow and, in fact, promote the movement of oxygen-rich tears around and underneath them.

Your eye care professional can prescribe HDS HI 1.54™ rigid gas permeable contact lenses in a variety of prescriptions and designs depending upon your vision correction needs. In addition, your eye care professional will determine what type of wearing schedule is best suited for you. HDS HI 1.54™ are for daily wear only.

PRECAUTIONS

Specific Precautions

- Clinical studies have demonstrated that HDS HI 1.54™ (pahrifocon A) rigid gas permeable contact lenses are safe and effective for their intended use. Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens materials were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner must consider all factors that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive reduction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Patients should be instructed to follow the instructions below in order to prevent damage to their eyes or lenses.

Solution Precautions

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with HDS HI 1.54™ contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping HDS HI 1.54™ contact lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva, tap water or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

Handling Precautions

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eye care practitioner.
- Always handle your 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 your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions

- If the lens sticks (stops moving) on the eye, follow the recommended directions on “Care For A Sticking Lens” in this patient information booklet. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty lens case after removing the lens. Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

Topics To Discuss With The Eye Care Practitioner

- Ask your eye care practitioner about wearing your lenses during sporting activities.
- Always contact your eye care practitioner before using any medicine in your eyes.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

Who Should Know That The Patient Is Wearing Contact Lenses

- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

You should be informed that 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 of something in the eye such as a foreign body or scratched area
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- 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 these problems, **IMMEDIATELY REMOVE YOUR LENSES.**

If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **DO NOT** put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner. If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it. If the problem continues, you should **IMMEDIATELY** remove the contact lenses and consult your eye care practitioner.

When any of the above problems occurs, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. You should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage, including corneal scarring, opacification, blindness or loss of eye.

PERSONAL CLEANLINESS AND LENS HANDLING

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 substance 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.
- To avoid damaging your lenses, handle them with your fingertips, and be careful to avoid contact with your 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.

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 cracks.

Placing The Lens On The Eye

Work over a table, upon which is placed a clean towel. Do not place lenses on the eye while working over a sink.

For the right eye:

- Wet your right index finger with a drop of conditioning solution and place the contact lens front side down on your right index finger.
- Place the second finger of the left hand on the middle of the upper lid and press upward firmly.
- Place the second finger of the right hand on the lower lid and press downward firmly.
- Stare into a mirror as though looking through the second finger holding the contact lens. You will later learn to do this without a mirror.
- Slowly move the hand to advance the forefinger with the contact lens towards the cornea until the lens touches the cornea and release the lids.
- Release the lid and close the eye for a few seconds.

Repeat this procedure for the left eye.

There are other methods of lens placement. If the above method is difficult for you, your eye care practitioner will provide you with an alternate method.

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

1. The lens is not centered on the eye (see "Centering the Lens", next section in this booklet).
2. 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. Clean, rinse, disinfect, and place on the eye again.
 - b. The lens is on the wrong eye.

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care practitioner.

Centering The Lens

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow this procedure.

- First locate the lens by pulling away the lids.
- After the lens is found, gently press on the lid over the lens while looking away from the direction of the lens.
- Next look back towards the lens.

Removing The Lens

Always remove the same lens first.

- Wash, rinse, and dry your hands thoroughly.
- Work over a table with a clean towel. Do not remove lenses over a sink.
- Place the right index finger of the right hand at the outer corner of the eye.
- Place the left hand cupped below the eye.
- Open the eyes wide as if to stare.
- Continue to keep the eyes open and pull the lids sideways away from nose.
- Blink quickly and firmly.

Remove the second lens by following the same procedure.

Follow the required lens care procedures described under the heading: CARING FOR YOUR LENSES.

Note: If this method of removing your lens is difficult for you, your eye care practitioner will provide you with an alternate method.

CARING FOR YOUR LENSES

Basic Instructions

For continued safe and comfortable wearing of your lenses, it is important that you clean and rinse, then disinfect your lenses after each removal using the care regimen recommended by your eye care practitioner. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean, rinse, and disinfect your lenses is immediately after wearing 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 on page 3.

When you first receive your lenses, practice how to put the lenses on and removing them while you are in your eye care 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 eye care practitioner should instruct you about appropriate and adequate procedures and products for your use.

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

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

Always use fresh unexpired lens care solutions.

Use the recommended system of lens care, which is chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**

Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

To avoid contamination, do not use saliva, tap water or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

Your eye care practitioner will recommend his/her preferred, FDA approved lens care solutions for the cleaning, disinfection, storage and lubrication of your HDS HI 1.54™ rigid gas permeable contact lenses.

Follow the instructions provided with each lens care solution. Failure to adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless it has been determined by the eye care practitioner that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

1. Clean

Clean one lens first (always start with the same lens first to avoid mix-ups). Place the lens, front side down, in the palm of the hand and apply several drops of cleaning solution. Using the index finger of the other hand, apply slight pressure in a swirling motion for the time recommended by the cleaning solution manufacturer. Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Do not clean the lens by rubbing it between the thumb and index fingers, as this may cause lens warpage.

2. Rinse

Rinse the lens thoroughly as recommended by your lens care product manufacturer to remove the cleaning solution, mucus, and film from the lens surface. Place that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

3. Disinfect

After cleaning and rinsing the lenses disinfect them by using the system recommended by your eye care practitioner and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.

Note: HDS HI 1.54™ contact lenses cannot be heat (thermally) disinfected.

4. Storage

To store lenses, disinfect and leave them in the closed case until ready to wear. Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. They should discard their solution immediately after their lenses have been removed from the lens case. They should not store their lenses in or rinse their lens case with tap water, bottled water or any non-sterile solution. If lenses are not to be used immediately following disinfection, you should consult the storage solution package insert or your eye care practitioner for information on storage of your lenses.

Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.

5. Care of Your Lens Case

Contact lens cases can be a source of bacteria growth. After removing your lenses from the lens case, empty the case. Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner. When the case is used again, refill it with fresh disinfecting solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

6. Lubricating/Rewetting

Your eye care practitioner will recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to rewet (lubricate) your lenses while you are wearing them to make them more comfortable.

Lens Deposits And Use Of Enzymatic Cleaning Procedure

Enzyme cleaning may be recommended by your eye care 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 your lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does not replace routine cleaning and disinfecting. For enzyme cleaning, you should carefully follow the instructions in the enzymatic cleaning labeling.

Care For A Sticking (Nonmoving) Lens

If the lens sticks (stops moving) or cannot be removed, you should apply 5 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 nonmovement of the lens continues after 30 minutes, you should IMMEDIATELY consult your eye care practitioner.

EMERGENCIES

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

- FLUSH EYES IMMEDIATELY WITH TAP WATER.
- REMOVE YOUR LENSES.
- IMMEDIATELY CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WEARING SCHEDULE

THE WEARING SCHEDULE SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. People tend to overwear contact lenses initially. It is important to adhere to the initial wearing schedule and never wear your lenses beyond the maximum recommended hours. Regular checkups, as determined by the eye care practitioner, are also very important.

NOTE: HDS HI 1.54™ contact lenses should be only worn on a daily wear schedule.

DO NOT sleep in these lenses.

The maximum suggested wearing times for HDS HI 1.54™ rigid gas permeable contact lenses are indicated in the following tables.

Wearing Schedule For Daily Wear

DAY	1	2	3	4	5	6	7	8	9	10-14	15 and after
ALLOWED HOURS	3	4	5	6	7	8	9	10	11	12	ALL daylight hours as needed
HOURS WORN											

WARNING

Risk of eye injury can be reduced by carefully following directions for routine lens care, including cleaning of the lens storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers.

It is recommended that contact lens wearers see their eye care practitioner twice each year or, if directed, more frequently.

HOW SUPPLIED

Each HDS HI 1.54™ lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Boston SIMPLUS® solution. This solution contains poloxamine, hydroxylalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). The case, packing slip or invoice is marked with the base curve, dioptric power, diameter, center thickness, lot number, fill date and the color of the lens.

* Boston SIMPLUS® is a registered trade mark of Bausch & Lomb.

Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Fill Date. When a lens has been stored for 30 days in its original packaging solution, it should be cleaned and disinfected with an FDA approved product, and placed into inventory as you presently do with any other RGP lens held in your office. Follow the directions on the selected disinfecting solution regarding prolonged storage.

Manufacturer:

Paragon Vision Sciences, Inc.
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