

Package Insert

Westcon Contact Lens
Horizon™ Products Package Insert
Horizon 55 EW and Horizon 55 EW Westint (methafilicon A)
Soft Hydrophilic Contact Lens for Extended Wear

IMPORTANT:

Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, but should be made available to the patient upon request. The eye care practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

Description:

The Horizon 55 EW and Horizon 55 EW Westint (methafilicon A) Soft Hydrophilic Contact Lens for extended wear is a hemispherical shell. It has varied base curves and diameters and powers as follows:

Base Curve:	8.0mm to 9.2mm	Center Thickness:	.06mm to .29mm
Diameter:	14.0mm to 15.0mm	Optic Zone:	4.0mm to 11.0mm
Power:	-20.00 to +10.00 Diopters		

The lens consists of 45% methafilcon and 55% water by weight when immersed in buffered saline solution. When the lens blank is tinted blue, the color additive Copper Phthalocyanine Blue Pigment will be added.

The physical/optical properties of the lens:

Specific Gravity:	1.09
Refractive Index:	1.411
Light Transmittance:	> 70%
Water Content:	55%
Oxygen Permeability	$D_k = 18.83 \times 10^{-11} \text{ (cm}^2/\text{sec) ml O}_2/\text{ml x mmHg at 25}^\circ\text{C.}$

Note: Oxygen Permeability measured by Schema Versatae model 920 connected to a polarographic cell.

Actions:

When placed on the human cornea in its hydrated state, the lens acts as a corrective refracting medium to focus light rays on the retina.

Indications:

The **Horizon 55 EW and Horizon 55 EW Westint** contact lenses in clear or with blue visibility tint are indicated for extended wear from 1 to 7 days between removal for cleaning, rinsing and disinfecting as recommended by the eye practitioner. The lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lenses may be worn by persons who exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the Horizon 55 EW 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, conjunctive, 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 lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses 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 Horizon 55 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:

The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that the lens is worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning the lens case.

Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses 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 lenses** and promptly contact your eye care practitioner.

All contact lens wearers must see their eye care practitioner as directed. When your lenses are for extended wear, your eye practitioner may prescribe more frequent visits.

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

PRECAUTIONS:

Special Precautions for eye care practitioner:

Clinical studies have demonstrated that contact lenses manufactured from (methafilcon A) are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens 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 should be carefully weighed against the patient's need for refractive correction: therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use. Wait at least one hour before replacing the lens. Too early replacement may allow the lenses to absorb residual fluorescein irreversibly.

Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

The eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lenses only. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions.
- Only chemical (not heat) lens care systems can be utilized for the Horizon 55 EW contact lenses manufactured from the (methafilcon A) material.
- Heat disinfection or use of potassium sorbate/sorbic acid preservative solutions with the **Horizon Contact Lenses** is not recommended and may damage the lenses.
- 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 wetting lenses.

- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage the lenses. 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 eye care practitioner.
- 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.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, 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 the Patient Instructions for the Horizon 55 Contact Lens and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses 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 eye care 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.

ADVERSE REACTIONS:

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pains.
- 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) or 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 the patient notices any of the above, he or she should be instructed to:
IMMEDIATELY REMOVE LENSES.

- If discomfort or problems stops, then look closely at the lens. If the lens has any damage, **DO NOT PUT THE LENS BACK ON THE EYE.** Place the lens in the storage case and contact the eye practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses: then reinsert them. After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE PRACTITIONER.**
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.

FITTING:

Conventional methods of fitting contact lenses do apply to the Horizon 55 Contact Lenses. For a detailed description of the fitting techniques, refer to the Horizon 55 Professional Fitting and Information Guides, copies of that are available from:

WESTCON CONTACT LENS COMPANY, Inc.
611 Eisenhower St.
Grand Junction, CO 81505
1 (800) 346-4303

WEARING SCHEDULE:

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

Extended Wear

Day One	6 hrs	Day Four	12 hrs
Day Two	8 hrs	Day Five	14 hrs
Day Three	10 hrs	Day Six	1-7 days

Basic Instructions:

Care of contact lenses takes very little time and involves **THREE** essential steps – **CLEANING, RINSING AND DISINFECTION**. Each step in itself is important, and one step is not to be replaced by the other. Always wash, rinse and dry hands before handling contact lenses. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Chemical disinfecting (**NOT HEAT**) of the contact lens is necessary to remove potentially harmful microorganisms. Use only the recommended system of lens care, 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**. Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth. Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfecting solution prior to disinfecting the lenses.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

Note: The eye practitioner should recommend a care system that is appropriate for the Horizon 55 Contact Lens. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

Note: Heat disinfection or use of potassium sorbate/sorbic acid preservative solutions with the **Horizon Contact Lenses** is not recommended and may damage the lenses.

- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline 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 and rinsing, **disinfect** lenses using the system recommended by the eye care practitioner.
- To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfecting, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the eye care practitioner; 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 your eye care practitioner.
- Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- **Horizon 55 EW Contact Lenses CANNOT** be heat (thermally) disinfected.

Chemical (NOT HEAT) Disinfecting:

- Wash and rinse your hands thoroughly **BEFORE HANDLING LENSES**.
- After removal of lenses, **CLEAN** the lenses by applying three drops of cleaner to each surface. Then rub the lens between your fingers for 20 seconds.

- AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
- Fill contact lens carrying case with the recommended disinfection and storage solution and place lenses in the proper cells as recommended in the labeling for the storage solution.
- Note: **DO NOT HEAT THE DISINFECTION SOLUTION AND LENSES.**
- 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 saline solution prior to placement on the eye should reduce the potential for irritation.

LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacteria growth. After removing the lenses 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 eye care practitioner.

CARE FOR DEHYDRATED LENSES

If for some reason, the lenses 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 recommended.

CARE FOR A STICKING NONMOVING 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.

HOW SUPPLIED:

Each lens is supplied sterile in a glass vial containing sterile normal saline solution USP, buffered with sodium bicarbonate USP. The glass vial is labeled with the base curve, diameter, diopter power, manufacturing lot number, and expiration date of the lens.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the lenses should be reported to:

WESTCON CONTACT LENS COMPANY, Inc.
611 Eisenhower St.
Grand Junction, CO 81505
1-800-346-4303

CAUTION: Federal Law Prohibits Dispensing without a Prescription.

**PATIENT
INSTRUCTION / WEARER'S GUIDE**

For all HORIZON Products
Including (clear or tinted):

HORIZON SOFT SPHERICAL & TORIC Daily Lenses
HORIZON 55 BI-CON & BI-CON TORIC Bi-Focal Daily Lenses

HORIZON 55 EW and HORIZON 55 EW WESTINT
(For Extended Wear)

Manufactured from 55% (methaficon A)

**Westcon Contact Lens Co., Inc.
611 Eisenhower St.
Grand Junction, CO 81505
970-245-3845**

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2. *Introduction*

You have just received your new **Horizon Contact Lens**. 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.

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

Your **Horizon Contact Lens** is made of a stable, inert, highly purified, hydrophilic (water absorbing) polymer with properties different from conventional hard lenses. Tooled to optical precision in the dry state, your lens holds these qualities in the soft, moist state in which it is 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 over wear the lenses simply because they remain comfortable. Your eye care practitioner will determine your appropriate wearing schedule.

Although soft and pliable, your lens is strong and durable. The life of **Horizon 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 Patient Instruction/Wearer's Guide carefully. It contains the information you need to know to wear, handle, and care for your **Horizon Contact Lens**. If you are in doubt about any instructions, request clarification from your eye care practitioner.

3. *Wearing Restrictions and Indications*

The **HORIZON 55 BI-CON** Contact lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, or hyperopic and are presbyopic.

The **HORIZON 55 BI-CON TORIC** Contact lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic, possess refractive astigmatism not exceeding 4.00 Diopters, and are presbyopic.

The **HORIZON SPHERICAL** Contact lens is indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigmatism of 1.5 diopters or less that does not interfere with visual acuity.

The **HORIZON TORIC** Contact lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic or for refractive astigmatism not exceeding 10 diopters that does not interfere with visual acuity.

The **Horizon 55 EW** and **Horizon 55 EW Westint** contact lenses in clear or with blue visibility tint are indicated for extended wear from 1 to 7 days between removal for cleaning, rinsing and disinfecting as recommended by the eye practitioner. The lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lenses may be worn by persons who exhibits astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

Note: The Horizon 55 lens may be disinfected using a chemical disinfecting system only. **NO HEAT DISINFECTION ALLOWED.**

4. *Contraindications, Warnings and Precautions*

4.1 CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Horizon 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, conjunctive, 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 lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, is a solution that is to be used to care for the **Horizon Contact Lens**.
- Any active corneal infection (bacterial, fungi, or viral)
- If eyes become red or irritated.
- You are unable to follow the lens care regimen or unable to obtain assistance to do so.

4.2 WARNINGS:

- 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 direction and all labeling instructions for proper use of lenses 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 LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**
- You must see your eye care practitioner as directed.
- Daily wear lenses are not indicated for overnight wear, and you are instructed not to wear the prescribed daily wear **Horizon Contact Lenses** while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- The following risk can be reduced by carefully following directions for routine lens care, including cleaning the lens case:

The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that the lens is worn between removals, beginning with the first overnight use.

4.3 PRECAUTIONS:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lenses only. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions.
- Only chemical (not heat) lens care systems can be utilized for the Horizon 55 EW contact lenses manufactured from the (methafilcon A) material.
- Heat disinfection or use of potassium sorbate/sorbic acid preservative solutions with the **Horizon Contact Lenses** is not recommended and may damage the lenses.
- 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 wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage the lenses. 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 eye care practitioner.
- 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.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, 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 the Patient Instructions for the Horizon 55 Contact Lens and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses 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 eye care 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.

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) or 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 LENSES.**

If discomfort or problems stops, then look closely at the lens. If the lens is in any damage, **DO NOT PUT THE LENS BACK ON YOUR EYE.** Place the lens in the storage case and contact your eye 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 lenses: then reinsert them. After reinsertion, if the problem continues, you should **IMMEDIATELY REMOVE THE LENSES AND CONSULT YOUR EYE CARE 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.

5. *Personal Cleanliness and Lens Handling*

6.1 Before Handling Your lenses:

Cleanliness is an important aspect of contact lens care.

Before handling your lenses, 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 lenses. When hair spray is used, the eye must be kept closed until the spray has settled. Take care in handling your lenses. Always avoid touching your lenses with your fingernails or other sharp objects. **NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.**

6.2 Handling and Placing the Lenses 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 saline 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) While looking down, and keeping both eyes open, 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 removed 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 solution to the eye and blink a few times. If the lens does not move freely on your eye, contact your eye care practitioner for further instructions.

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

6.3 Removing the lenses:

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 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 eye care 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 LENSES. 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 eye care practitioner will suggest another method or provide additional instruction.

NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.

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 eye care practitioner.

6. Caring for Lenses

7.1 Basic Instructions:

For continued safe and comfortable wearing of your lenses, it is important that you **first 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 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 warnings section above.

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

When you first get your lenses, be sure you have to put the lenses on and remove them while you are in your eye care practitioner's office. At that time you will be provided with a recommended cleaning and disinfecting regimen and instructions and warnings for lens care, handling, cleaning, and disinfecting. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Patient Instruction / Wearer's Guide for the **Horizon Contact Lenses**.

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, sterile, unexpired** lens care solutions.
- Use recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling.
- Heat disinfection or use of potassium sorbate/sorbic acid preservative solutions with the **Horizon Contact Lenses** is not recommended and may damage the lenses.
- 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.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the 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 the lens down the drain.

The eyecare practitioner should recommend a care system that is appropriate for the **Horizon 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 saline 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 and rinsing, **disinfect** lenses using the system recommended by your eye care practitioner.
- To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the package insert or your eye care practitioner for information on storage of 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 after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.
- **Horizon Contact Lenses cannot be heat (thermally) disinfected.**

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

7.2 Lens Deposits And Use Of Enzymatic Cleaning Procedure:

The eyecare practitioner may recommend enzyme cleaning. 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 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, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

7.3 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 nonmovement of the lens continues after 15 minutes, you should IMMEDIATELY consult your eye care practitioner.

7.4 Chemical (NOT HEAT) Disinfection:

1. Wash and rinse your hands thoroughly BEFORE HANDLING LENSES.
2. After removal of lenses, CLEAN the lenses 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 rinsing solution for approximately 10 seconds.
4. Fill contact lens carrying case with the recommended disinfection and storage solution and place lenses in the proper cells as recommended in the labeling for the storage solution.

Note: DO NOT HEAT THE DISINFECTION SOLUTION AND LENSES.

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

WARNING: Heat disinfection or use of potassium sorbate/sorbic acid preservative solutions with the Horizon Contact Lenses is not recommended and may damage the lenses.

7.5 Lens case cleaning and maintenance:

Contact lens cases can be a source of bacteria growth. After removing the lenses 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 eye care practitioner.

7.6 Care for a Dried out (dehydrated) dry Lens:

If for some reason, your lenses dry out completely, a minimum of handling is very 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.

7.7 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 EYE CARE 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 eye care practitioner if:

- 1) Your eyes become 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 eye care practitioner.

Learn and Use Proper lens Care Habits:

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

8. *Wearing Schedule*

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

Day One	6 hrs	Day Four	12 hrs
Day Two	8 hrs	Day Five	14 hrs
Day Three	10 hrs	Day Six *	

*Daily Wear: all waking hrs.

*Extended Wear: 1-7 days

9. *Appointment Schedule*

Month	Year	Time	Day
_____	_____	_____	_____
_____	_____	_____	_____

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 PRACTITIONER IMMEDIATELY.**

CAUTION: Federal Law Prohibits Dispensing without a Prescription.

10. **SPECIFIC BI-CON INSTRUCTIONS:**

Specific Bi-focal instructions, explanations and demonstrations are important for successful adaptation. The following procedures and instructions will prove useful in the wear of your new **Horizon Bi-Con Contact Lenses**.

- 1) As for soft contact lenses in general, you should have realistic expectations of their likely success with **Horizon Bi-Con Contact Lenses**.
- 2) Initially, upon lens insertion and dispensing, you may experience subjective blurring of vision at either distance or near. Often, this may be called a hazy border around objects, a ghost image or shadowing. However, visual acuity of 20/15 or 20/20 under these circumstances is not unusual. This problem is over-come by adaptation which may occur in 30 minutes but in most cases is usually complete at the one week or perhaps one month visit. This adaptation is analogous to that experienced by first time bi-focal spectacle wearers, noticing frame or segment effects.
- 3) Distance visual problems can be expected to be most noticeable under bright light conditions for the **Horizon Bi-Con Contact Lenses**. This is due to normal pupil constriction in bright light resulting in light being focused primarily by the near zone. A useful demonstration in the doctor's office can be achieved by you comparing the chart clarity and appearance of second images under darkened conditions and then bright lit conditions. This demonstration is recommended so that you are not surprised by the changes in vision that occur in various lighting conditions. For **Horizon Bi-Con Contact** wearers, plano sunglasses under bright conditions reduces the vision fluctuation noted at a distance.
- 4) For some patients, it will be necessary to adapt to the appearance of flare around lights during night vision. Under normal circumstances, you are advised that you will adapt to this occurrence within a few weeks of wear. After this adaptation period, you will typically concede that the flare around lights is still present but no longer bothersome.
- 5) It is suggested that you travel as a passenger rather than driver the first time you travel by car at night after **Horizon Bi-Con Contact Lenses** dispensing. This will enable you to experience any unusual visual effects before driving.
- 6) With careful fittings, eye care practitioners can achieve good success with **Horizon Bi-Con Contact Lenses**. A realistic visual expectation for you is that bifocal distance and near visual acuity's will be similar or perhaps slightly reduced compared to spectacles.
- 7) As with all soft contact lenses, your motivation is an important factor in both predicting and achieving patient success.

Patient Rev -04

PROFESSIONAL FITTING AND INFORMATION

Horizon 55 EW and Horizon 55 EW Westint
(methafilicon A) Soft Hydrophilic
Contact Lenses

Caution: Federal Law Prohibits Dispensing without a Prescription

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INTRODUCTION:

The **Horizon 55 EW and Horizon 55 EW Westint** soft hydrophilic contact lenses are made from copolymer with water content 55% by weight.

For a complete listing of available lens parameters, please refer to Lens Parameters Available.

PRODUCT DESCRIPTION:

The lens consists of 45% methafilcon and 55% water by weight when immersed in buffered saline solution. When the lens blank is tinted blue, up to .8 % of the color additive Copper Phthalocyanine Blue Pigment will be added to the MA. The color additive conforms to 21 CFR Part 74.3045.

LENS PARAMETERS AVAILABLE:

Base Curve:	8.0mm to 9.2mm	Center Thickness:	.06mm to .29mm
Diameter:	14.0mm to 15.0mm	Optic Zone:	4.0mm to 11.0mm
Power:	-20.00 to +10.00 Diopters		

The lens consists of 45% methafilcon and 55% water by weight when immersed in buffered saline solution. When the lens blank is tinted blue, the color additive Copper Phthalocyanine Blue Pigment will be added.

The physical/optical properties of the lens:

Specific Gravity: 1.09
 Refractive Index: 1.411
 Light Transmittance: > 70%
 Water Content: 55%
 Oxygen Permeability $D_k = 18.83 \times 10^{-11}$ (cm²/sec) ml O₂/ml x mmHg at 25°C.
 Note: Oxygen Permeability measured by Schema Versatae model 920 connected to a polarographic cell.

ACTIONS:

When placed on the human cornea in its hydrated state, the lens acts as a corrective refracting medium to focus light rays on the retina.

INDICATIONS:

The **Horizon 55 EW and Horizon 55 EW Westint** contact lenses in clear or with blue visibility tint are indicated for extended wear from 1 to 7 days between removal for cleaning, rinsing and disinfecting as recommended by the eye practitioner. The lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lenses may be worn by persons who exhibits astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

CONTRAINDICATIONS. WARNINGS. PRECAUTIONS. AND ADVERSE REACTIONS SECTIONS:

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the Horizon 55 EW 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, conjunctive, 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 lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses 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 Horizon 55 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:

The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that the lens is worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning the lens case.

Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses 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 lenses** and promptly contact your eye care practitioner.

All contact lens wearers must see their eye care practitioner as directed. When your lenses are for extended wear, your eye practitioner may prescribe more frequent visits.

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

PRECAUTIONS:

Special Precautions for eye care practitioner:

Clinical studies have demonstrated that contact lenses manufactured from (methafilcon A) are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens 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 should be carefully weighed against the patient's need for refractive correction: therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use. Wait at least one hour before replacing the lens. Too early replacement may allow the lenses to absorb residual fluorescein irreversibly.

Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

The eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lenses only. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions.
- Only chemical (not heat) lens care systems can be utilized for the Horizon 55 EW contact lenses manufactured from the (methafilcon A) material.
- Heat disinfection or use of potassium sorbate/sorbic acid preservative solutions with the **Horizon Contact Lenses** is not recommended and may damage the lenses.
- 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 wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage the lenses. 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 eye care practitioner.
- 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.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, 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 the Patient Instructions for the Horizon 55 Contact Lens and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses 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 eye care 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 lenses.
- 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.

ADVERSE REACTIONS:

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pains.
- 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) or 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 the patient notices any of the above, he or she should be instructed to:

- **IMMEDIATELY REMOVE LENSES.**
- If discomfort or problems stops, then look closely at the lens. If the lens has any damage, **DO NOT PUT THE LENS BACK ON THE EYE.** Place the lens in the storage case and contact the eye practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses: then reinsert them. After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE PRACTITIONER.**
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.

SELECTION OF PATIENTS:

Patients who require visual correction but cannot adhere to the recommended care of the Horizon 55 EW should not be provided with this lens. Patient communication is vital. All necessary steps in the lens care and all precautions and warnings should be discussed and understood by the patient. Review the package insert with the patient.

FITTING PROCEDURE:

1.0 Pre-Fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for extended wear contact lenses (consider patient hygiene and mental and physical state),
- make ocular measurements for the initial contact lens parameter selection,
- collect and record baseline clinical information to which post-fitting examination results can be compared,

Preliminary examinations should include the patient's refraction and keratometric readings. The lens parameters are determined from the (k) readings:

Base Curve	K Readings
8.3	46.00 to 48.00
8.6	42.00 to 45.75
8.9	38.00 to 41.75

Use initial diameter of 14.5

If diameter is increased by .5mm, flatten base curve by .3mm

If diameter is decreased by .5mm, steepen base curve by .3mm

2.0 INITIAL LENS EVALUATION

See CRITERIA OF A WELL-FITTED LENS

3.0 FOLLOW-UP CARE

Prior to a follow-up examination, the contact lenses should be worn for at least 24 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

- a. Record any patient symptoms related to contact lens wear.
- b. Examine lids and conjunctiva.
- c. Check visual acuity and refract over the lens. Acuity and over-refraction should be checked on two different days before making a power change.

- d. With lenses in place on the eyes, evaluate fitting performance to CRITERIA OF A WELL FITTED LENS. Examine the lenses closely for surface deposits and/or damage.
- e. After the lens removal, conduct a thorough biomicroscopy examination.
 - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
 - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
 - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
- f. If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

RECOMENDED INITIAL WEARING SCHEDULE:

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

Extended Wear

Day One	6 hrs	Day Four	12 hrs
Day Two	8 hrs	Day Five	14 hrs
Day Three	10 hrs	Day Six	1-7 days

CLINICAL ASSESSMENT:

1. CRITERIA OF A WELL-FITTED LENS

- Limbus to limbus coverage, both during normal eye position and when the lids are held apart manually.
- In the primary gaze, slight (1mm or less) but definite vertical post-blinking movement of the lens.
- Clear, regular and stable keratometric mires when observed through the instrument with the lens in place.
- A 0.5 to 1.5 mm lag upon upward and/or lateral gaze; no resistance to movement when direct digital manipulation of the lens is applied.
- Clear, stable visual acuity with the over-refraction in place.
- Satisfactory comfort response by the patient.

2. Characteristics of a Tight (Steep) Lens
 - Bubble(s) under the lens, indicating vaulting.
 - Conjunctival capillary blanching and scleral indentation followed by injection during and after wear.
 - No post-blink movement.
 - No lens movement when eye gazes upward or laterally; resistance to movement when direct manipulation of the lens is applied.
 - Blurred vision, which clears briefly, immediately following the blink.
 - Variable, irregular, blurry keratometric mires over the lens, which may clear immediately after the blink.
 - Good Initial comfort.
3. Characteristics of a Loose (Flat) Lens
 - Excessive lens movement after the blink.
 - Excessive decentration of lens with limbal exposure in the primary position of gaze.
 - Lower lid sensation.
 - Edge buckling and stand-off observable at or near the lower lid margin.
 - Variable visual acuity.
 - Excessive lens lag often associated with upper lid sensation on upward gaze.
 - Variable, "foggy, hazy" keratometric mires with the lens in place.

PATIENT LENS CARE DIRECTIONS:

Basic Instructions:

Care of contact lenses takes very little time and involves **THREE** essential steps – **CLEANING, RINSING AND DISINFECTION**. Each step in-itself is important, and one step is not to be replaced by the other. Always wash, rinse and dry hands before handling contact lenses. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Chemical disinfecting (**NOT HEAT**) of the contact lens is necessary to remove potentially harmful microorganisms. Use only the recommended system of lens care, 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 SOLUTIONS UNLESS INDICATED ON SOLUTION LABELING**. Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth. Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to

destroy harmful germs. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfecting solution prior to disinfecting the lenses.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

Note: The eye practitioner should recommend a care system that is appropriate for the Horizon 55 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 saline 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 and rinsing, **disinfect** lenses using the system recommended by the eye care practitioner.
- To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfecting, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of lenses.
- Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- **Horizon 55 EW Contact Lenses CANNOT** be heat (thermally) disinfected.

Chemical (NOT HEAT) Disinfecting:

- Wash and rinse your hands thoroughly **BEFORE HANDLING LENSES**.
- After removal of lenses, **CLEAN** the lenses by applying three drops of cleaner to each surface. Then rub the lens between your fingers for 20 seconds.
- **AFTER CLEANING**, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
- Fill contact lens carrying case with the recommended disinfection and storage solution and place lenses in the proper cells as recommended in the labeling for the storage solution.

- **Note: DO NOT HEAT THE DISINFECTION SOLUTION AND LENSES.**

Heat disinfection or use of potassium sorbate/sorbic acid preservative solutions with the **Horizon Contact Lenses** is not recommended and may damage the lenses.

- **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 saline solution prior to placement on the eye should reduce the potential for irritation.

LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacteria growth. After removing the lenses 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 eye care practitioner.

CARE FOR DEHYDRATED LENSES

If for some reason, the lenses 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 recommended.

CARE FOR A STICKING (NON-MOVING) LENS:

If the lens sticks on the eye (cannot be removed), 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.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the lenses should be reported to:

WESTCON CONTACT LENS COMPANY, Inc.
611 Eisenhower St.
Grand Junction, CO 81505
1-800-346-4303

HOW SUPPLIED:

Each lens is supplied sterile in a glass vial containing sterile normal saline solution USP, buffered with sodium bicarbonate USP. The glass vial is labeled with the base curve, diameter, power, manufacturing lot number, and expiration date of the lens.

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