

PATIENT INSTRUCTION / WEARER'S GUIDE



Custom Stable™ Rigid Gas Permeable Scleral Contact Lens for Daily Wear

***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 **Custom Stable™ Rigid Gas Permeable Scleral 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 contact lens.

PRACTITIONER: _____

ADDRESS: _____

TELEPHONE: _____

Parameters	TYPE	POWER	DIAM.	BC	LOT#
Right					
Left					

Disinfection Solution: _____

Rinsing Solution: _____

Daily Cleaner: _____

Lubricating Solution: _____

Enzymatic Cleaner: _____

INTRODUCTION:

Your **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** is made of a highly purified, hydrophobic polymer with properties different from conventional rigid lenses. Tooled to optical precision, 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 contact lenses simply because they remain comfortable. Your eye care practitioner will determine your appropriate wearing schedule.

The life of your **Custom Stable™ Rigid Gas Permeable Scleral 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 device.

Read this Wearer's Guide carefully. It contains the information you need to know to wear, handle, and care for **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens**. If you are in doubt about any instructions, request clarification from your eye care practitioner.

WEARING RESTRICTIONS and INDICATIONS:

Indication for Use:

The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lenses** for daily wear are indicated for use for the management of multiple ocular conditions, such as, degenerations that lead to an irregular corneal shape (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's Nodular Degeneration), dystrophies (e.g. Cogan's dystrophy, granular corneal dystrophy, Lattice Corneal Dystrophy), post-surgery (e.g. corneal transplant, LASIK, radial keratotomy), and corneal scarring. The lens may also be prescribed for the management of ocular surface diseases (e.g. dry eye syndrome, Keratoconjunctivitis Sicca (Graft vs Host Disease, Sjogren's syndrome, Filamentary Keratitis), limbal stem cell deficiency, epidermal ocular disorders, neurotrophic keratitis, and corneal exposure/lagophthalmos). When prescribed for therapeutic use, the Custom Stable RGP Scleral Lenses is also indicated for correction of refractive error in persons with myopia, hyperopia or presbyopia.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

DO NOT WEAR CUSTOM STABLE™ RIGID GAS PERMEABLE SCLERAL CONTACT LENSES WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lenses** when any of the following conditions exist:

- * Acute and subacute inflammation or infection of the anterior chamber of the eye.
- * Any systemic disease that may affect the eye or be exaggerated by wearing the contact lens.
- * Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing the contact lenses or use of care solutions.
- * Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lenses**.
- * Any active corneal infection (bacterial, fungal, or viral)
- * If eyes become red or irritated.
- * You are unable to follow the care regimen or unable to obtain assistance to do so.

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 **Custom Stable™ Rigid Gas Permeable Scleral 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.

PRECAUTIONS:

- * **CAUTION – Non-sterile.** Clean and condition lenses prior to use.
- * 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. Chemical

- disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in chemical disinfection only. 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 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.
- * If the lens sticks (stops moving) on the eye, follow the recommended directions on **Care For Sticking (non-moving) 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 microscope scratches of the lenses 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 **Custom Stable™ Rigid Gas Permeable Scleral Contact Lenses** 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) 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 LENSES.**

- * 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 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.

- * During use for the management of irregular corneal conditions, an adverse effect may be due to the original condition or may be due to the effect of wearing a contact lens. There is a possibility that the existing condition might become worse when a lens is used on an eye with an irregular cornea condition. The patient should be instructed to avoid serious eye damage by contacting the eye care professional **IMMEDIATELY** if there is an increase in symptoms while wearing the lens.

PERSONAL CLEANLINESS and LENS HANDLING

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 that 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.

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 rinsing solution. Then place the lens on the tip of the index finger of your dominant hand.
- 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 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 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.

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, gently pull at the corner of low/upper lids, the lens should fall out.
- 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 lenses 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, 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.

CARING FOR YOUR LENSES

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** after lens wear is necessary to remove mucus, secretions, films, or deposits which may have accumulated during wear. The ideal time to clean your lenses is immediately 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 learn to comfortably 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 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, and provide you with a copy of the Wearer's Guide for the **Custom Stable™ Rigid Gas Permeable Scleral 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 the 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 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 eye care practitioner should recommend a care system that is appropriate for the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lenses**. 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 and rinsing, **disinfect** lenses using the system recommended by the manufacture and/or 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.
- * **Custom Stable™ Rigid Gas Permeable Scleral Contact Lenses** can be disinfected using only a chemical (NOT HEAT) disinfecting system.

- * 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.
- * 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.

Specific Instructions for Use and Warnings:

a. Soaking and Storing Your Lenses

Instruction for Use:

- Use only fresh multi-purpose (contact lens disinfecting) solution each time you soak (store) your lenses.

WARNING:

- Do not reuse or “top off” old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness.
- “Topping-Off” is the addition of fresh solution to solution that has been sitting your case.

b. Rub and Rinse Time

Instruction for Use:

- Rub and rinse your lenses according to the recommended lens rubbing and rinsing times in the labeling of your multi-purpose solution to adequately disinfect your lenses.

WARNING:

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

c. Lens Case Care

Instruction for Use:

- Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without

any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.

- Replace your lens case according to the directions given you by your eye care professional or the labeling that came with your case.
- Contact lens cases can be a source of bacterial growth.

WARNING:

- Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

d. Water Activity

Instruction for Use:

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

WARNING:

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water when swimming in pools, lakes or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

e. Discard Date on Multipurpose Solution Bottle

Instruction for Use:

- Discard any remaining solution after the recommended time period indicated on the bottle of multipurpose solution used for disinfecting and soaking your contact lenses.
- The Discard date refers to the time you can safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

WARNING:

- Using your multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.
- To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.
- To avoid contaminating your solution, DO NOT transfer to other bottles or containers

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 eye care practitioner.

Chemical (NOT HEAT) Lens Disinfection:

1. Wash and rinse your hands thoroughly **BEFORE HANDLING LENSES**.
2. After removal of lenses, **CLEAN** the lenses by applying three drops of cleaning solution 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 unexpired** rinsing solution for approximately 10 seconds.
4. Fill contact lens case with the recommended disinfection and storage solution and place lenses in the proper cells for the time specified in the solution label.

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

- When using hydrogen peroxide lens care systems, **use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution.** Failure to use the specialized case will result in severe stinging, burning, and injury to the eye. Follow the recommendations on the hydrogen peroxide system labeling exclusively. Following disinfection with a peroxide system, the lenses should be rinsed with sterile saline.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

The eye care 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 daily 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 lenses 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 disinfecting solution. Replace lens case at regular intervals as recommended by the lens case manufacture or your eye care practitioner.

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 EYECARE 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 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 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) Disinfection is a Necessary Security.

WEARING SCHEDULE:

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

Close supervision by the eye care professional is necessary. The eye care professional should determine the appropriate wearing time and provide specific instructions to you regarding care, insertion and removal.

APPOINTMENT SCHEDULE:

Your appointments are on:

Month Year Time Day

IMPORTANT:

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

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