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# Device Information



## 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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**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 device.

**DESCRIPTION OF DEVICE**

The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** for daily wear is a large diameter rigid gas permeable contact lens design that vaults over the cornea and rests on the conjunctiva overlying the sclera. The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** is lathe cut from one FDA-approved hydrophobic, fluoro-silicone acrylate materials:

Examples of the physical properties of the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** are as follows:

	<b>ROFLUFOCON D</b>	<b>ROFLUFOCON E</b>
<b>Refractive Index</b>	1.430	1.4332
<b>Light Transmission (clear)</b>	>97%	>97%
<b>Light Transmission (tinted)</b>	>90%	>90%
<b>Water Content</b>	<1%	<1%
<b>Dynamic Contact Angle (Receding)</b>	3°	6°
<b>Specific Gravity</b>	1.166	1.155
<b>Modulus</b>	697 MPa	77 MPa
<b>Shore D Hardness</b>	75	77
<b>Oxygen Permeability (Dk) ISO/FATT Method</b>	$100 \times 10^{11} \text{ (cm}^2\text{/sec)}$ (ml O <sub>2</sub> /ml x mm Hg @ 35° C)	$125 \times 10^{11} \text{ (cm}^2\text{/sec)}$ (ml O <sub>2</sub> /ml x mm Hg @ 35° C)

<b>contain one or more of the following color additives conforming to: 21 CFR Part 73 &amp; 74, Subpart D</b>	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18
<b>UV Light Blocking (UVB – 280nm – 315nm; UVA 316nm – 380nm)</b>	>98% UVB >95% UVA	>98% UVB >95% UVA

The parameters for the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** are as follows:

- \* Chord Diameter: 13.8 mm to 19.0 mm
- \* Center Thickness: 0.20 mm to 1.20 mm
- \* Base Curve: 6.6 mm to 11.0 mm
- \* Spherical Powers: -30.00 Diopters to +30.00

Diopters

(0.125 Diopter steps)

## ACTIONS

When placed on the eye for therapeutic use, the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** replaces or supports impaired ocular surface function. Incidentally, the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** acts as a refracting media to focus light rays on the retina.

## CAUTION

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

### **CAUTION:**

**FEDERAL LAW RESTRICTS THIS DEVICE TO SALE  
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Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or parameters available in the material are not evaluated in significant numbers. Consequently, when selecting an appropriate design and parameters, the eye care practitioner should consider all characteristics of the device that can affect device performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive correction; therefore, the continuing

ocular health of the patient and device performance on the eye should be carefully monitored by the prescribing eye care practitioner.

## INDICATIONS

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.

## CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** when any of the following conditions are present:

- \* 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 device.
- \* Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing the device 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 **Custom Stable™ Rigid Gas Permeable Scleral Contact Lenses**.
- \* If the devices are shipped wet, allergy to any active ingredient in Unique pH Disinfecting & Storage Solution, Boston Advance Comfort Formula Conditioning Solution, or Boston SIMPLUS Multi-Action solution.
- \* Any active corneal infection (bacterial, fungi, or viral)
- \* If eyes become red or irritated.
- \* Patients unable to follow care regimen or unable to obtain assistance to do

so.

## WARNINGS

- \* PROBLEMS WITH CONTACT LENSES AND 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 the device and care products, including the storage 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 DEVICE** AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.
- \* All contact lens wearers must see their eye care practitioner as directed.
- \* Daily wear contact lenses are not indicated for overnight wear, and patients should be instructed not to wear the device while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these devices are worn overnight.
- \* 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 and/or physician:

**WARNING** Inspect packaging for leakage when contact lenses are wet shipped in Unique pH Disinfecting & Storage Solution (rofluocon D & E), Boston Advance Comfort Formula Conditioning Solution (oprifocon A & hexafocon B), or Boston SIMPLUS Multi-Action solution (oprifocon A & hexafocon B). If the packaging is damaged or leaking, throw away damaged packaging and replace with a new container and refill with new cleaning, disinfection and storage solution.

Prior to dispensing, it is important to THOROUGHLY RINSE all storage solution from the contact lens since it will sting and cause irritation if instilled directly in the eye. After rinsing is complete and prior to inserting into patients eye, apply 2 drops of rewetting drops to each surface WITHOUT rubbing the device.

When the contact lenses are shipped/stored wet, the solution needs to be replaced with new storage solution every 30 days from initial manufacture date. The new solution shall be Fresh, Sterile, Unexpired and from a newly opened bottle.

- \* For the most accurate fluorescein interpretation, it is recommended that the blue cobalt and the yellow Wratten filter be used. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use.

- \* Thoroughly rinse the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** with fresh, sterile saline or rinsing solution prior to insertion.
- \* Before leaving the eye care practitioner's office, the patient should be able to promptly remove the contact lens or should have someone else available who can remove the lens for him or her.
- \* Eye care practitioners should instruct the patient to remove the contact lens immediately if the eye becomes red or irritated.

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.

Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection. Always use **FRESH, STERILE UNEXPIRED** care solutions. Always follow directions in the package inserts for the use of care solutions. Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions. Do not use saliva or anything other than the recommended solution for lubricating or rewetting the lenses. Always keep the lens completely immersed in the recommended storage solution when they are not being worn (stored). Prolonged periods of drying will damage the lens. Follow the care directions for a dried out (dehydrated) contact lens if the surface does become dried out.

- \* Always wash and rinse hands before handling devices. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on the contact lens before putting on makeup. Water-base cosmetics are less likely to damage the lens than oil-base.
- \* Do not touch the contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the devices 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 Lens** and those prescribed by the eye care practitioner.
- \* Never wear the device beyond the period recommended by the eye care practitioner.
- \* If aerosol products such as hair spray are used while wearing the contact

- lens, exercise caution and keep eyes closed until the spray has settled.
- \* Always handle the contact lenses carefully and avoid dropping them.
  - \* Avoid all harmful or irritating vapors and fumes while wearing the lenses.
  - \* Ask the eye care practitioner about wearing the contact lenses during sporting activities.
  - \* Inform the doctor (health care practitioner) about being a contact lens wearer.
  - \* Never use tweezers or other tools to remove the lens from the 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 the lenses.
  - \* 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 pain.
- \* Comfort is less than when the contact 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 the patient notices any of the above, he or she should be instructed to:

- \* **IMMEDIATELY REMOVE THE LENS.**
- \* If discomfort or problems stops, then look closely at the lenses. If the lens is in any way damaged, **DO NOT PUT THE DEVICE BACK ON THE EYE.** Place the contact 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 device appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lens: 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 THE CONTACT LENSES OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.

During therapeutic use, an adverse effect may be due to the original disease or injury or may be due to the effects of wearing the contact lenses. There is a possibility that the existing disease or condition might become worse when a contact lens is used to treat an already diseased or damaged eye. The patient should be instructed to avoid serious eye damage by contacting the eye care professional **IMMEDIATELY** if there is any increase in symptoms while wearing the device.

**FITTING**

Conventional methods of fitting contact lenses do not apply to the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens**. For a detailed description of the fitting techniques, refer to **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens Professional Fitting and Information Guide**, copies of which are available from:

**Valley Contax, Inc.**  
4748 Franklin BVLD, Eugene Oregon 97403  
(800) 547-8815  
[contax@valleycontax.com](mailto:contax@valleycontax.com)

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**WEARING SCHEDULE**

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

Close professional supervision is necessary for therapeutic use of the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens**, and patient compliance will be critical to the success of this program. Since in these cases the cornea may already be compromised, the cornea must be examined carefully and monitored continually to ensure that the device is not interfering with the condition or healing process.



**STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE CUSTOM STABLE RIGID GAS PERMEABLE SCLERAL CONTACT LENS IS SAFE TO WEAR DURING SLEEP.**

## **CONTACT LENS CARE DIRECTIONS**

Eye care practitioners should review with the patient care directions, including both basic care information and specific instructions on the care regimen recommended for the patient:

**\* Basic Instructions:**

Care of the contact lens 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 the contact lens. Always use **FRESH, STERILE UNEXPIRED** care solutions. Use the recommended chemical (not heat) care system. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **DO NOT ALTERNATE OR MIX CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING.**

Do not use saliva or anything other than the recommended solutions for lubricating or rewetting the device. Do not put the device in the mouth. Contact lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the device surface. **Disinfecting** is necessary to destroy harmful germs. The case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lens. Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to rewet (lubricate) the lens while they are being worn to make them more comfortable.

**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.

**\* Specific Instructions for Use and Warnings:**

**a. Soaking and Storing the Contact Lens**

**Instruction for Use:**

- Use only fresh multi-purpose (disinfecting) solution each time the lenses are soaked (stored).

**WARNING:**

- Do not reuse or “top off” old solution left in the case since solution reuse reduces effective 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 the case.

**b. Rub and Rinse Time**

**Instruction for Use:**

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

**WARNING:**

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

**c. Contact 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 storage cases with fresh, clean tissue is recommended. Never air-dry or recap the 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 the contact lens case according to the directions given by the eye care professional or the labeling that came with the case.
- Cases can be a source of bacterial growth.

**WARNING:**

- Do not store the contact lens or rinse the contact lens case with water or any non-sterile solution. Only use fresh multi-purpose solution to prevent contaminating the devices or device case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

**d. Water Activity**

**Instruction for Use:**

- Do not expose the contact lenses to water while wearing them.

**WARNING:**

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the contact lenses have been submersed in water when swimming in pools, lakes or oceans, the patient should discard them and replace them with a new pair. The patient should ask the eye care practitioner (professional) for recommendations about wearing the 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 the contact lens.
- The Discard date refers to the time the patient can safely use 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 the 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 the solution, DO NOT transfer to other bottles or containers.

**\* Contact lens cleaning, rinsing, disinfection, and storage:**

**Clean** one contact lens first (always the same device first to avoid mix-ups), rinse the device thoroughly with recommended rinsing solution to remove the cleaning solution, mucus, and film from the surface, and put lenses into correct chamber of the contact lens storage case. Then repeat the procedure for the second lens. After cleaning and rinsing, **disinfect** contact lenses using the system recommended by the manufacture and/or the eye care practitioner. To store device, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of contact lenses.

**\* Contact Lens Care Regimen:**

Patients must adhere to the care regimen recommended by their eye care practitioner for the care of **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens**. Failure to follow this procedure may result in development of serious ocular infections

\* **Storage:**

The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** must be stored in the individual plastic case and in the recommended solutions.

\* **Chemical (NOT HEAT) Disinfection:**

1. Wash and rinse your hands thoroughly BEFORE HANDLING LENSES.
2. After removal, **CLEAN** the lens 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 the device case with the recommended disinfection and storage solution and place devices in the proper cells for the time specified in the solution label.

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

Caution: Contact 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 care systems, **the patient must use ONLY the 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.

## **DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE**

The eye care practitioner may recommend enzyme cleaning. Enzyme cleaning removes protein deposits on the lenses. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the wellbeing of the

patient's device and eyes. If these deposits are not removed, they can damage the lens 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.

## RECOMMENDED SOLUTIONS

**Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** should be disinfected using only a chemical (not heat) disinfection system. The following care systems are recommended (or other care systems as recommended by your eye care practitioner).

Lenses made in	Contamac Materials (Optimum Extra, Optimum Extreme)
SYSTEM PROCESS	CHEMICAL (not heat) DISINFECTION SYSTEM
Daily Cleaning	Menicon Unique pH Multi-Purpose Solution
Cleaning, Disinfecting and Soaking.	Menicon Unique pH Multi-Purpose Solution
Wetting & Lubricating	Boston Rewetting drops
Protein Remover	Menicon Progent Protein Remover

## EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should:

**FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

## HOW SUPPLIED:

The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** may be shipped “dry” or “wet” in a polypropylene contact lens case. The primary container for shipping the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** is the Bonasse Flat Bed Soaking Case, Model SC-107. The **Custom Stable™ Rigid Gas**

**Permeable Scleral Contact Lens** may also be shipped in the Amcon screwcap case, Model SC-106, or the Amcon snapdown case, Model JC-4013.

When shipped “wet”, The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** manufactured from oprifocon A or hexafocon B may be packaged and shipped in Boston Advance Comfort Formula Conditioning Solution or Boston SIMPLUS Multi-Action solution. The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** manufactured from roflufocon D or E may be packaged and shipped “wet” in in the Menicon Unique pH multipurpose solution.

The case, packing slip and invoice are marked with the base curve, dioptic power, diameter, center thickness, color, lot number and the initial packaging date.

#### **REPORTING OF ADVERSE REACTIONS:**

Practitioners should report any adverse reactions within 5 days to Valley Contax, Inc. Additional Fitting Guides, Package Inserts and Patient Guides are available from:

**Valley Contax, Inc.**  
4748 Franklin BVLD  
Eugene, OR 97403  
(800) 547-8815  
[contax@valleycontax.com](mailto:contax@valleycontax.com)

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