

PACKAGE INSERT

OPTIMUM GP (rofluocon A, C, D & E)
Rigid Gas Permeable (RGP) CONTACT LENSES
FOR DAILY WEAR

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

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 this package insert along with the prescribed contact lens package insert to the patient to insure proper care.

DESCRIPTION OF LENSES

The **OPTIMUM GP** series of contact lenses are fabricated from the hydrophobic contact lens materials (rofluocon A), (rofluocon C), (rofluocon D), & (rofluocon E). When placed on the human cornea, the OPTIMUM GP rigid gas permeable contact lenses act as a refracting medium to focus light rays upon the retina.

The **OPTIMUM GP** Contact Lens for Daily Wear are available as lathe cut contact lenses with spherical, aspheric, bifocal, multifocal or toric anterior and/or posterior designs in clear and tinted versions.

The **OPTIMUM GP** contact lens may be packaged and shipped wet in the Optimum Cleaning, Disinfecting and Storage (CDS) GP solution. The product is a sterile solution containing lauryl sulfate salt of imidazoline octylphenoxy polyethoxyethanol, and preserved with benzyl alcohol (0.3%) and disodium edetate (0.5%).

The **OPTIMUM GP** Contact Lens for Daily Wear is a rigid gas permeable methacrylate copolymer of Methyl methacrylate, 1,1,1,3,3,3 - Hexafluoroisopropyl Methacrylate, Methacryloxypropyl Tris(trimethylsiloxy) silane, 1,3-bis(methacryloxypropyl)-1,1,3,3-tetrakis(trimethyl siloxy)disiloxane, 2-Dihydroethyl Methacrylate, and Methacrylic acrylic acid cross-linked with Ethylene Glycol Dimethacrylate. The OPTIMUM GP Contact Lens for Daily Wear incorporates a visibility tint to make the lens more visible for handling. The tinted lenses contain one or more of the following color additives: D&C Green No.6, C.I. Solvent yellow No. 18, and FD&C Red No. 17.

UV Blocker

In the **OPTIMUM GP** Contact Lens with UV Blocker, a Benzophenone UV blocker is used to block UV radiation. The UV Blocker is 2,2'-Dihydroxy-4,4'-dimethoxybenzophenone. The UV blocking for OPTIMUM GP averages > 98% in the UVB range of 280nm – 315nm and 95% in the UVA range of 316 – 380nm.

The physical properties of the **OPTIMUM GP** Contact Lens are:

Physical Property	(rofluocon A)	(rofluocon C)	(rofluocon d)	(rofluocon e)
Refractive Index	1.4527	1.4406	1.4333	1.4332
Light Transmission (clear)	>97%	>97%	>97%	>97%
Light Transmission (tinted)	>90%	>90%	>90%	>90%
Wetting Angle (Dynamic contact receding angle)	12°	6°	3°	6°
Specific Gravity	1.189	1.178	1.166	1.155
Oxygen Permeability (Dk) ISO/FATT Method	26	65	100	125
Visitint lenses contain one or more of the following color additives	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	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

Lens parameters:

Spherical, Toric, Multifocal/Bifocal, Keratoconus and Large Diameter Scleral -

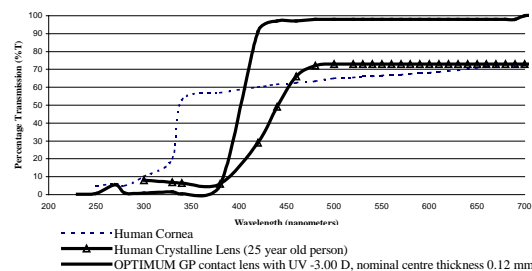
- * Chord Diameter: 7.0 mm to 22.0 mm
- * Center Thickness: Varies
- * Base Curve: 5.0 mm to 8.0 mm
- * Spherical Powers: -20.00 Diopters to +20.00 Diopters
- * Toric Powers: up to -10.00 Diopters cylinder
- * Add Powers: up to + 4.00 Diopters

WARNING: UV-blocking contact lenses are NOT substitutes for protective UV-blocking eyewear such as UV-blocking goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-blocking eyewear as directed.

The following graph compares the UV transmittance profile of the **OPTIMUM GP** (rofluocon A, C, D & E) Rigid Gas Permeable Contact Lens, -3.00 D & .06mm thick, to that of a cornea and crystalline lens. Data was obtained from measurements taken through the central 3-5mm portion of the thinnest marketed version of the UV lens.

Cornea - Human cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58. **Crystalline Lens** - Human crystalline lens from a 25-year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

Typical Transmittance Profile of -3.00 D OPTIMUM GP Contact Lens with UV versus a Human Cornea and Human Lens.



NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye-care practitioner for more information.

ACTIONS

When placed on the cornea, the OPTIMUM GP (RGP) Contact Lens acts as a refracting media to focus light rays on the retina.

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

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Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare 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 must 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 eyecare practitioner.

INDICATIONS

The **OPTIMUM GP** (rofluocon A, rofluocon C, rofluocon D, and rofluocon E) **Spherical** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be disinfected with a chemical disinfection system only.

The **OPTIMUM GP** (rofluocon A, rofluocon C, rofluocon D, and rofluocon E) **Toric** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters. The lens may be disinfected with a chemical disinfection system only.

The **OPTIMUM GP** (rofluocon A, rofluocon C, rofluocon D, and rofluocon E) **Multifocal/Bifocal** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The lens may be disinfected with a chemical disinfection system only.

The **OPTIMUM GP** (rofluocon A, rofluocon C, rofluocon D, and rofluocon E) **Keratoconus** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear and may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or following refractive (e.g. LASIK) surgery. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons. The lens may be disinfected with a chemical disinfection system only.

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 OPTIMUM GP Contact Lenses when any of the following conditions are present:

- * Acute and subacute inflammation or infection of the anterior chamber of the eye.
- * Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- * Aphakic patients should not be fitted with OPTIMUM GP (RGP) Contact Lenses until the determination is made that the eye has healed completely.
- * Severe insufficiency of lacrimal secretion (dry eyes).
- * Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- * 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 OPTIMUM GP (RGP) Contact Lenses.
- * Allergy to any active ingredient in Optimum by Lobob cleaning, disinfecting and storage solution, such as lauryl salt of imidazoline octylphenoxy polyethoxyethanol, benzyl alcohol 0.3% and disodium edetate 0.5%, if lenses are shipped wet
- * Any active corneal infection (bacterial, fungi, or viral)
- * If eyes become red or irritated.
- * Patients unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

- * **PROBLEMS WITH CONTACT 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.
- * Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear 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

Special Precautions for eye care practitioner and/or physician:

Inspect contact lens packaging for leakage when lenses are wet shipped in Optimum by Lobob cleaning, disinfecting and storage solution. If the packaging is damaged or leaking, throw away damaged packaging and replace with a new contact lens container and refill with new cleaning, disinfection and storage solution.

Prior to dispensing, it is important to THOROUGHLY RINSE all OPTIMUM GP Cleaning, Disinfecting and Storage solution from the 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 OPTIMUM Wetting and Rewetting Drops to each surface of the lens WITHOUT rubbing the lens.

Lenses that are shipped/stored wet in Optimum by Lobob Cleaning, Disinfecting and Storage solution: The solution needs to be replaced with new Optimum by Lobob Cleaning, Disinfecting and Storage solution every 30 days from initial manufacture date. The new Optimum GP solution shall be Fresh, Sterile, Unexpired and from a newly opened bottle.

- * Clinical studies have demonstrated that contact lenses manufactured from (rofluocon A, C, D & E) 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. The continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

- * 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 OPTIMUM GP lenses 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 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.

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.

Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection. Always use **FRESH, STERILE UNEXPIRED** lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions. Do not use saliva or anything other than the recommended solution for lubricating or

rewetting 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 (non-moving) Lenses**. The lens should move freely on the eye for the continued health of the eye. If nonmovement 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 OPTIMUM GP (RGP) 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 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 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 is in any way damaged, **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 and do not apply to OPTIMUM GP (RGP) Contact Lens. For a detailed description of the fitting techniques, refer to OPTIMUM GP (RGP) Professional Fitting and Information Guide, copies of which are available from the Contact Lens Manufacturer.

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to over wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.

The maximum suggested wearing schedule for the OPTIMUM GP (RGP) Contact Lens is reflected below.

DAY	HOURS
1	3
2	4
3	5
4	6
5	7
6	8
7	9
8	10
9	11

10 – 14
15+ 12
All waking hours

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE OPTIMUM GP (RGP) CONTACT LENS IS SAFE TO WEAR DURING SLEEP.

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

LENS CARE DIRECTIONS

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

* 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. Use the recommended chemical (not heat) lens 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 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 disinfection solution prior to disinfecting the lenses. Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to rewet (lubricate) lenses 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 Lenses

Instruction for Use:

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

WARNING:

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

b. Rub and Rinse Time

Instruction for Use:

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

WARNING:

- Rub and rinse the lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the 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 the lens case according to the directions given by the eye care professional or the labeling that came with the case.
- Contact lens cases can be a source of bacterial growth.

WARNING:

- Do not store the lenses or rinse the lens case with water or any non-sterile solution. Only use fresh multi-purpose solution to prevent contaminating the 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 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 lenses have been submerged 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 lenses.
- The Discard date refers to the time the patient 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 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.

* Lens cleaning, rinsing, disinfection, and storage:

Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended rinsing 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 manufacturer and/or 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 disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of lenses.

* 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, fill it with fresh disinfecting solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

* Lens Care Regimen:

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the care of OPTIMUM GP (RGP) Contact Lens. Failure to follow this procedure may result in development of serious ocular infections

* Care for a sticking (non-moving) lens:

If the lens sticks (cannot be removed), the patient should be instructed to 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, the patient should **IMMEDIATELY** consult the eye care practitioner.

* Storage:

The OPTIMUM GP (RGP) Contact lenses must be stored in the individual plastic case and in the recommended solutions.

* 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 the 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.

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

RECOMMENDED SOLUTIONS

OPTIMUM GP lenses should be disinfected using only a chemical (not heat) disinfection system. The following lens care systems are recommended (or other lens care systems as recommended by your eye care practitioner).

SYSTEM PROCESS	CHEMICAL (not heat) DISINFECTION SYSTEM
Daily Cleaning	Lobob OPTIMUM GP extra strength cleaner
Cleaning, Disinfecting and Soaking.	Lobob OPTIMUM C/D/S
Wetting & Lubricating	Lobob OPTIMUM GP wetting and rewetting

Product List –

1. OPTIMUM GP Daily Cleaner, OPTIMUM GP W/RW (wetting & rewetting solution), OPTIMUM GP C/D/S (cleaning, disinfecting, soaking solution) by Lobob Laboratories.

PURCHASE SOLUTIONS ON THE INTERNET AT: WWW.LOBOBLABS.COM

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:

Each lens is supplied non-sterile in an individual plastic case. The **OPTIMUM** GP contact lens may be packaged and shipped wet in the Optimum Cleaning, Disinfecting and Storage (CDS) GP solution. The product is a sterile solution containing lauryl sulfate salt of imidazoline octylphenoxy polyethoxyethanol, and preserved with benzyl alcohol (0.3%) and disodium edetate (0.5%).

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 Contamac US, Inc. Additional Package Inserts are available from:

www.contamac.com

Contamac US, Inc.

Telephone # (866) 872 6682 or (970) 242 3669

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United Kingdom

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