

PACKAGE INSERT

FOR THE

HYBRID FS

(HYBUFOCON A)

GP (OXYGEN PERMEABLE)

CONTACT LENS FOR DAILY 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 patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTION

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

DESCRIPTION

The Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear is a rigid gas permeable random copolymer of (3-methacryloxypropyl) tris (trimethylsiloxy) saline, bis (methacryloxypropyl) tetrakis (trimethylsiloxy) disiloxane, hexafluoroisopropyl methacrylate, 2,2,2,-trifluoroethyl methacrylate, methyl methacrylate, 2-hydroxyethyl methacrylate, glycerol monomethacrylate and acrylic acid cross-linked with allyl methacrylate and triethylene glycol dimethacrylate with no UV absorber. The Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear incorporate a visibility tint to make the lens more visible for handling.

The Hybrid FS (hybufocon A) RGP Contact Lens for Daily Wear is a hemispherical shell of the following dimensions:

Power Range: +20.00 to -20.00D
Base Curve: 5.00mm to 9.50mm
Diameter: 8.4mm — 12.0mm
Center Thickness:
for low minus lens: 0.13mm (-3.00D)
for plus lens: 0.28mm (+3.00D)
Back optic zone radius: 7.0 — 8.5mm
Add powers: +1.00D to +3.75D, in 0.5D increments
Prism Ballast: 0.5 to 3.5 prism Diopters in 0.5D increments
Toricity: Up to 9.00 Diopters

The physical/optical properties of the lens are:

Specific Gravity:	1.183 (wet)
Refractive Index:	1.4465 ± 0.002
Light Transmittance:	95% Minimum tinted 96% Minimum clear
Surface Character:	Hydrophobic
Wetting Angle (CLMA):	Not measurable after 24 hours hydration (Captive bubble method)
Water absorption (%):	<0.94%
Oxygen Permeability:	
31 x 10 ¹¹ (cm ² sec [ml O ₂ /(ml x mm Hg)] at 350 C	
(Dk) measured on single lenses by the Fatt method (ISO9913-1).	

ACTIONS

In its hydrated state the Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear when placed on the cornea acts as a refracting medium to focus light rays on the retina. The lens also provides a more even surface over slightly uneven or astigmatic cornea thereby neutralizing minor corneal deformations, this in turn helps to focus light rays on the retina in a more regular fashion.

INDICATIONS (USES)

The Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic or not-aphakic persons with non-diseased eyes and may be presbyopic.

The lens may be disinfected using chemical disinfection only.

CONTRAINDICATIONS (REASONS NOT TO USE)

Do NOT use the Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear if any of the following conditions exist:

- Acute and sub-acute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- 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, eye lubricants or rewetting drops.
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated.

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- 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. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- 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 non-smokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact their eye care practitioner. It is recommended that contact lens wearers see their eye care professional routinely as directed.

PRECAUTIONS

Caution: NON-STERILE. Clean and condition lenses prior to use.

Special Precautions for Eye Care Practitioners:

- 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 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.

- Aphakic patients should not be fitted with Hybrid FS (hybufocon A) RGP Contact Lens for Daily Wear until the determination is made that the eye has healed completely.
- 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.
- Fluorescein may be used to determine the fit of the Hybrid FS (hybufocon A) RGP Contact Lens for Daily Wear on the eye.

Eye care practitioners should carefully instruct patients about the following care regime 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.
- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear.
- 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 solutions for lubricating or wetting.
- 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 lenses. Follow the lens care direction for Care for a Dried Out (Dehydrated) Lens if lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a 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 products.
- 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, disposal and wearing instructions in the Patient Instructions for the Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear 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 in the eyes.
- Always inform the employer of being ~ contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- Certain medications may cause dryness of the eye, increased lens awareness or blurred vision. These include but are not limited to antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness. If any of these symptoms occur, remedial action should be prescribed. Depending on the severity, this could include the use of lubricating drops or temporarily discontinuing contact lens wear while such medication is being used.
- 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 might occur when wearing contact lenses:

- 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 eyes.
- Unusual eye secretions.
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbow, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.
- Poor visual acuity, blurred vision, rainbows, or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.
- Temporary impairment due to infiltrates, peripheral corneal ulcers and corneal erosion. There may be potential for other physiological observations such as local or generalized edema, corneal neovascularization, corneal staining, injections, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.

If the patient notices any problems, he or she should be instructed to:

practitioner) and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

- The eye care practitioner should recommend a care system that is appropriate for the Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

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.

- Clean one lens first (always the same lens first to avoid mix-ups), rinse and lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eye care practitioner.
- To store lenses, 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.
- After removing the lenses from the lens 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 storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.
- Eye care practitioners may recommend a Lubricating/Re-wetting solution which can be used to wet lenses while they are being worn to make them more comfortable.
- The Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear cannot be heat (thermally) disinfected.

CHEMICAL LENS DISINFECTION:

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eye care practitioner.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.

Daily Cleaner:	<ul style="list-style-type: none"> • OPTIMUM by LOBOB® 'Extra Strength' Cleaner
Disinfecting Solution:	<ul style="list-style-type: none"> • OPTIMUM by LOBOB® Cleaning/Disinfection/Storage Solution.
Lubricant/ Rewetting Drops:	<ul style="list-style-type: none"> • OPTIMUM by LOBOB® Wetting, Re-Wetting Drop and In the Eye Lubricant

*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 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 disinfection. For enzyme cleaning the patient should follow the instructions in the enzymatic cleaning labeling.

RECOMMENDED LENS CARE PRODUCTS

The eyecare practitioner should recommend a care system that is appropriate for the Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear Contact Lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. For optimal

and enhanced performance, Contamac recommends 'OPTIMUM' solutions by Lobob for use with the Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear Contact Lenses.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacterial and micro-organism growth. Lens cases should be emptied, cleaned, rinsed with solution recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks, stops moving or cannot be removed, the patient should be instructed to apply 2 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 5 minutes, the patient should immediately consult the eye care practitioner.

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 in a flat pack mailer. Each package is marked with the brand (trade) name, regulatory information, base curve, diopter power, diameter, center thickness, color, and lot number.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear or experienced with the lenses should be reported to:

Contamac US, Inc.,
2214 Sanford Drive, Suite B7
Grand Junction, CO 81505
866-872-6682

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- Immediately remove lenses.
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Discard the lens and insert a fresh new lens on the eye. Place the lens in the storage case and contact the eyecare practitioner.
- If the lens has dirt, an eyelash, or other foreign body on it, the patient should be instructed to thoroughly clean and rinse the lenses then reinsert them, as advised by the eye care practitioner.
- 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 lenses off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING & DISPENSING

Conventional methods of fitting contact lenses apply to Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear. For a detailed description of the fitting techniques, refer to the Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear Professional Fitting and Information Guide, copies of which are available from:

Contamac US, Inc.,
623 Glacier Drive
Grand Junction, CO 81503
866-872-6682

PREPARING AN RGP LENS FOR FITTING:

Wash hands and rinse off all traces of soaps, hand cleaner, moisturizers etc. Remove lens from storage container and rinse thoroughly with fresh soaking and wetting solution or sterile saline.

Inspect the lens to ensure no damage is evident. If inspection equipment is available, verify the lens parameters such as diameter, base curve and power. Place a little soaking and wetting solution or sterile saline in the bowl of the posterior surface ready for insertion.

WEARING SCHEDULE

The eye care practitioner should determine the wearing and replacement schedules. 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 check-ups, as determined by the eye care practitioner, are also extremely important.

Contamac recommends that the lens be discarded and replaced with a new lens every month. However, the eye care practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

The Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear is indicated for daily wear of less than 24 hours while awake. The suggested wearing time for these lenses is four to six hours on the first day, then add two to four hours per day until all-day wear is achieved. Time may need to be adapted according to the patient's response.

Studies have not been completed to show that the Hybrid FS Spherical, Toric and Multifocal (hybufocon A) RGP Contact Lens for Daily Wear are safe to wear during sleep.

LENS CARE DIRECTIONS

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

General Lens Care (to first clean and rinse, then disinfect lenses).

BASIC INSTRUCTIONS:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.
- Use 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 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.
- Always remove, clean, rinse, enzyme (as recommended by the eyecare