

PACKAGE INSERT

ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses

IMPORTANT: PLEASE READ CAREFULLY AND RETAIN FOR FUTURE USE

This package insert is intended for the eyecare practitioner, but should be made available to patients upon request. The eyecare practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner. This Package Insert applies to all ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses.

DESCRIPTION: ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses are available in spherical designs in the clear untinted or blue, green, blue-violet (onzure) and gray tinted varieties, and blue with UV-blocker. Each is a shell of the following dimensions.

Spherical Contact Lens:

Horizontal Lens Size: 6.5 mm to 11.50mm

Base Curve: 6.50mm to 9.50mm

Distance Powers: +12.00D to -20.00D

Center Thickness: for low minus 0.05mm to 0.30mm for plus 0.10mm to 0.70mm

Aspheric Lens

Eccentricity 0 to 1.5

Peripheral Curves 0.1 to 1.0mm

Toric Lens

Axis 1 to 180 degrees in 1 degree steps

Cylinder power 0.50 to 4.00D

Translating Bifocal Contact Lens:

Horizontal Lens Size: 8.00mm to 10.50mm

Base Curve: 6.50mm to 8.50mm

Distance Power: +12.00D to -20.00D

Add Power 1.00 to 4.00D

The lens material, onsifocon A is a fluorosilicone acrylate copolymer with additional hydrophilic and crosslinking monomers. The blue tinted lenses contain D&C Green No. 6; the green lenses contain D&C Green No 6 and CI Solvent Yellow 18; the gray lenses contain D&C Green No 6, D&C Violet No. 2, and CI Solvent Yellow 18; the blue-UV lenses contain D&C Green No 6 and a UV absorber. The colorants are used in quantities approved for use in contact lenses and proportions required to obtain the desired color. The physical properties of the lenses are as follows:

Typical Property Test Value

Hardness D/85 (Shore HardnessUnits)

Water Content <1.0%

Wetting Angle 7.2° (sessile drop method)

Oxygen Permeability 56.2 ANSI units

Dimensional Stability Stable

Refractive Index 1.452

Specific Gravity 1.206

Light Transmission Clear >95%T

Blue >70%T*

Green >70%T*

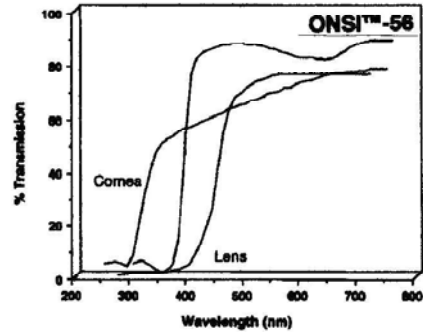
Gray >70%T*

Blue-UV >70%T* 400-780nm, 0% T 200-380nm

Mechanical(flexural strength) 3952 psi

*The wearer may experience a reduction in visibility while wearing the lens in conditions of low illumination.

The following graph compares the UV transmittance curve of the ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens, Blue-UV, 0.12mm thick) to that of the human cornea of a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig 2-21, and that of the human crystalline lens from a 25 year old, as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, fig 5.



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-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

Warning: UV-absorbing contact lenses are **NOT** substitutes for protective UV-absorbing eyewear such as UV-absorbing sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

ACTIONS: The ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses each, when placed on the cornea, acts as a refracting medium to focus light rays onto the retina.

INDICATIONS: The ONSIJ-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic and which may exhibit corneal astigmatism. The lenses may be disinfected by using chemical disinfection only.

CONTRAINDICATIONS: DO NOT USE the ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens when any of the following conditions exist:

- * Acute or subacute inflammation of the cornea, the iris or the anterior chamber of the eye.
- * Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- * Insufficiency of lacrimal secretion (dry eyes).
- * Corneal hypesthesia (reduced corneal sensitivity)
- * Any systemic disease which 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 must be used to care for the ONSI™-56 (onsifocon A) lenses.

* Any active corneal infection: bacterial, fungal 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 contact lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products. 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 nonsmokers.

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 his or her eye care practitioner.

ALL CONTACT LENS WEARERS MUST RETURN FOR PERIODIC CHECK-UP VISITS AS RECOMMENDED BY THEIR EYE CARE PRACTITIONER.

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

Special Precautions for Eyecare Practitioners:

* Due to the small number of patients enrolled in clinical investigations of lenses, all refractive powers, design configurations, or lens parameters available in the lens materials 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 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 eyecare practitioner.

Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

Before leaving the eyecare 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.

Eyecare 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.

- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.

- Do not use heat or thermal lens care systems.

Heat disinfection will damage the lens.

-always use **fresh unexpired** lens care solution.

* **Always use a lens care system for your ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens which has been recommended for use with fluorosilicone acrylate contact lenses.**

-CONVENTIONAL HARD CONTACT LENS SOLUTIONS ARE NOT INDICATED FOR USE WITH THE ONSI™-56 (onsifocon A) RIGID GAS PERMEABLE SPHERICAL, ASPHERIC, TORIC AND BIFOCAL CONTACT LENS

- Always use FRESH rinsing and storage solutions.

-Always follow directions in the package insert for the use of each contact lens solution.

- 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 lenses.

- Always keep the lenses completely immersed in a recommended storage solution when the lenses are not being worn (stored).

Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions for Care for a Dried Out (Dehydrated) 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 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 and deodorants 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, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens and those prescribed by the eyecare practitioner.

* Never wear lenses beyond the period recommended by the eyecare 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 your lenses.

* Ask the eyecare practitioner about wearing lenses during sporting events.

* Inform the doctor (health care practitioner) about being a contact lens wearer.

* Never use tweezers or other tools to remove your 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 consult your eye care practitioner before using any medicine in your eyes.

* Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

* As with any contact lens, follow-up visits are necessary to assure continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

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

* Eyes sting, burn, itch (irritation) or other eye pain.

* Comfort is less than when lens was first placed on the eye.

* Feeling of something in the eye (foreign body, scratched area).

* Excessive watering (tearing) of the eye.

* Unusual eye secretions.

* Redness of the eyes.

* 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 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. Place the lens in the storage case and contact the eye care practitioner.

* If the lens has dirt, an eyelash, or other foreign body on it or the problem stops and the lens appears undamaged, thoroughly clean, rinse, and disinfect the lens with recommended solutions, and then reinsert it.

* After reinsertion, if the problem continues, the patient should immediately remove the lens and consult the eye care practitioner.

When any of the above symptoms or problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to keep the 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 rigid contact lenses apply to the ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens. For a detailed description of the fitting technique, refer to the Fitting and Information Guide, copies of which are available from Lagado.

PREPARING AN RGP LENS FOR FITTING

The ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens is shipped dry and non-sterile. It should be cleaned and conditioned according to the solution instructions prior to placing on the patient's eye.

WEARING SCHEDULE:

THE WEARING AND REPLACEMENT SCHEDULE SHOULD BE DETERMINED BY THE

EYECARE PRACTITIONER. Patients tend to over wear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular check-ups, as determined by the eyecare practitioner, are also extremely important.

The ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens is indicated for daily wear (during waking hours only).

The maximum suggested wearing time for these lenses is as follows:

Day	Hours
1	4
2	5
3	6
4	7
5	8
Day	Hours
6	9
7	10
8	11
9	12
10	all waking hours

Studies have not been completed to show that the lens is safe to wear during sleep. Do not wear ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses while sleeping.

LENS CARE DIRECTIONS:

Eyecare 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.

General Lens Care (To First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions

* Always wash and rinse your hands before handling contact lenses.

* Always use **fresh unexpired** lens care solutions.

* Use only a chemical system **recommended for fluorosilicone acrylate lenses** for lens care.

Different solutions cannot always be used together, and not all solutions are safe for all lenses.

Do not alternate or mix lens care systems unless indicated on the 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.

* Your lenses should be cleaned, rinsed and disinfected each time you remove them.

CLEANING and RINSING are necessary to remove mucus

and film from the lens surface. **DISINFECTING** is necessary to prevent growth of harmful germs.

* Always remove, clean, rinse, enzyme (as recommended by the eyecare practitioner) and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

* The following solutions have been used in clinical trials with the onsifocon A material. Your eye care practitioner may recommend alternative lens care products.

Contact Lens Care System Solution Purpose
Solution Brand Name*

Clean OPTIMUM Cleaning/Disinfecting/Storage Solution

Rinse Tap water

Disinfect/Store OPTIMUM

Cleaning/Disinfecting/Storage Solution

Rinse Rinse thoroughly as recommended by your eyecare practitioner

Lubricate/Rewet OPTIMUM by Lobob®

Wetting/Rewetting Drop

Extra Strength Cleaner OPTIMUM by Lobob®
"Extra Strength" Cleaner

The Package Insert accompanying each solution and the package label of each product provide detailed instructions on how the solutions are to be used in caring for contact lenses. Read and follow those instructions carefully. The ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses should only be disinfected by chemical systems of disinfection **specifically recommended for use with fluorosilicone acrylate lenses.**

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

* Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline, tap water 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 and rinsing, disinfect lenses using the system recommended by the manufacturer and/or eyecare practitioner.

* To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If the lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare 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 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 eyecare practitioner.

* Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

* ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses cannot be heat (thermally) disinfected. Chemical (Not Heat) Disinfection:

* Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.

* After cleaning and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the eyecare 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 eye.

* 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:

Enzyme cleaning may be recommended by the eyecare practitioner. 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 lens and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions 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 eyecare practitioner.

CARE FOR A STICKING (NONMOVING) LENS:

If the lens sticks (stops moving) or cannot be removed, the patient should be instructed to apply 5 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 30 minutes, the patient should immediately consult their eyecare practitioner.

EMERGENCIES:

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed onto the eyes, the patient should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED:

Each lens is supplied non-sterile in a plastic lens storage case containing one or two lenses. The container is marked with the patient name, base curve, distance power, diameter, center thickness, color, and lot number.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses or experienced with the lenses should be reported to The Lagado Corporation, 303-789-0933. Printed 10/04