

PACKAGE INSERT

(FOR DAILY WEAR CORNEAL AND SCLERAL CONTACT LENSES)

Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens

Spherical and Aspheric Contact Lenses for Myopia and Hyperopia
Toric Contact Lenses to Correct Astigmatism
Contact Lenses for the Management of Irregular Corneas
Multifocal Contact Lenses for Presbyopia
in Aphakic and Non-Aphakic People

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

IMPORTANT

Please read carefully and keep this information for future use. This package insert is intended for the eye care professional or practitioner, but should be made available to patients upon request. The eye care professional or practitioner should provide the patient with the patient instructions that pertain to the patient’s prescribed lens.

DESCRIPTION

The **Menicon Z™ (tisilfocon A)** Rigid Gas Permeable contact lens is available as a daily wear spherical, aspheric, toric or multifocal design.

Contact lenses for the management of irregular corneas are available for daily wear only.

The lens material (tisilfocon A) is a thermoset copolymer derived from fluoro-methacrylate and siloxanylstyrene, bound by crosslinking agents. The contact lenses are available in a clear and a light blue tint. The light blue lens is tinted with color additive D & C Green No. 6. Also, a UV absorber (Benzotriazol) is added as an additive during the manufacturing process.

The **Menicon Z™ (tisilfocon A)** contact lens is a hemispherical shell of the following dimensions (not all parameter combinations are available in all designs):

| Spherical and Aspheric Contact Lens | |
|---|--------------------------------------|
| Diameter | 9.1 to 20.0 mm |
| Center Thickness | 0.08 to 0.50 mm |
| Base Curve | 6.00 to 10.5 mm |
| Powers | -25.00 to +25.00 D (in 0.25 D steps) |
| Toric Contact lens | |
| Diameter | 9.1 to 20.0 mm |
| Center Thickness | 0.08 to 0.50 mm |
| Base Curve | 6.00 to 10.5 mm |
| Sphere Powers | -25.00 to +25.00 D (in 0.25 D steps) |
| Cylinder Powers | 0.00 to -10.00 D (in 0.25 D steps) |
| Prism Ballast | 0.75 to 2.00 D (in 0.25 D steps) |
| Truncation Height | 0.0 to 1.0 mm (in 0.1 mm steps) |
| Multifocal Contact Lens (Centered, Decentered, Crescent) | |
| Diameter | 9.1 to 20.0 mm |
| Center Thickness | 0.08 to 0.65 mm |
| Base Curve | 6.00 to 10.5 mm |
| Sphere Power | -25.00 to +25.00 D |
| Add Power | +1.00 to +3.50 D |

The physical/optical properties of the contact lenses are:

Specific Gravity: 1.20
Refractive Index: n ²⁰ 1.439
Surface Character: Hydrophobic
Wetting Angle: 51 degrees (after soaking)
Light Transmittance:

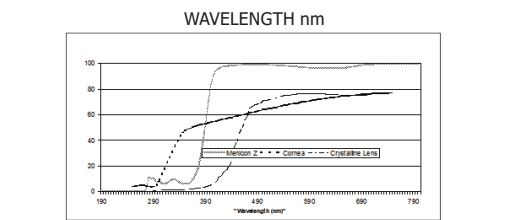
Visible region ≥80% (380 nm – 780 nm)
Ultraviolet region ≤5% (210 nm – 380 nm)
(sample thickness 0.2 mm)

Water Absorption: No more than 0.5% by weight
Oxygen Permeability:

163x10⁻¹¹ (cm²/sec)(mL O₂/(mL x mmHg)) Dk*

Hardness (Shore D): 83

* Method for determination of oxygen permeability: ISO 18369-4 2017. Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials



Menicon Z™ (tisilfocon A) contact lens:
- Spectral transmittance curve for the **Menicon Z™ (tisilfocon A)** contact lens
- D & C Green No. 6 and UV absorbing agent (sample thickness **Menicon Z™ (tisilfocon A)** contact lens polymer plate = 0.08 mm, representing the thinnest marketed version of the contact 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, figure 2-21.

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.

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 the eye care professional or practitioner for more information.

PRODUCT NAME LIST

All products in this list are manufactured of **Menicon Z™ (tisilfocon A)**. The information in this document applies for these products.

| Product Name | Abbreviation |
|--|----------------------------------|
| SynergEyes GP | SynergEyes GP |
| SynergEyes GP Front toric | SynergEyes GP FtrTor |
| SynergEyes GP Bitoric | SynergEyes GP Bitor |
| SynergEyes GP Bitoric Extra | SynergEyes GP Bitor Ext |
| SynergEyes GP Progressive D | SynergEyes GP Pro D |
| SynergEyes GP Progressive N | SynergEyes GP Pro N |
| SynergEyes GP Progressive D Plus | SynergEyes GP Pro D+ |
| SynergEyes GP EP | SynergEyes GP EP |
| SynergEyes GP Bitoric Extra Progressive | SynergEyes GP Bitor Ext D |
| SynergEyes GP Bitoric Progressive | SynergEyes GP Bitor Pro D |
| SynergEyes GP Bitoric Progressive Plus | SynergEyes GP Bitor Pro D+ |
| SynergEyes GP Bitoric Extra Progressive Plus | SynergEyes GP Bitor Ext Pro D+ |
| SynergEyes GP II | SynergEyes GP II |
| SynergEyes GP II Bitoric | SynergEyes GP II Bitor |
| SynergEyes GP II Bitoric Extra | SynergEyes GP II Bitor Ext |
| SynergEyes GP II EP | SynergEyes GP II EP |
| SynergEyes GP II Progressive D | SynergEyes GP II Pro D |
| SynergEyes GP II Progressive N | SynergEyes GP II Pro N |
| SynergEyes GP II Bitoric Progressive | SynergEyes GP II Bitor Pro D |
| SynergEyes GP II Bitoric EP | SynergEyes GP II Bitor EP |
| SynergEyes GP II Bitoric Extra Progressive | SynergEyes GP II Bitor Ext Pro D |
| SynergEyes GP II Bitoric Extra EP | SynergEyes GP II Bitor Ext EP |
| SynergEyes GP II Progressive D Plus | SynergEyes GP II Pro D+ |
| SynergEyes VS - Sphere | SynergEyes VS Sph |
| SynergEyes VS | SynergEyes VS |
| SynergEyes VS - MF | SynergEyes VS - MF |

ACTIONS

The **Menicon Z™ (tisilfocon A)** contact lens, when put on the cornea, acts as a refracting medium to focus light rays on the retina. The **Menicon Z™ (tisilfocon A) Scleral** contact lens, when put on the conjunctiva, vaults over the cornea and acts as a refracting medium to focus light rays on the retina.

The **Menicon Z™ (tisilfocon A)** contact lens is a lathe cut firm contact lens with spherical or aspheric back surfaces. The posterior curve is selected to properly fit an individual eye, and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the contact lens and cornea.

The **Menicon Z™ (tisilfocon A) Toric** contact lens provides a more even surface over the different curvatures of the astigmatic cornea and thus helps to focus light rays on the retina.

The **Menicon Z™ (tisilfocon A) Multifocal** contact lens provides the necessary optical powers to correct different refractive errors for distance and near requirements.

INDICATIONS

The **Menicon Z™ (tisilfocon A)** Rigid Gas Permeable contact lens is available as a spherical, aspheric, toric or multifocal design and is intended for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic disease-free eyes.

The contact lenses may be prescribed in spherical and aspheric powers ranging from -25.00 D to +25.00 D for daily wear.

The contact lenses may be prescribed for daily wear in

otherwise disease-free eyes that require rigid contact lenses for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery.

The contact lenses may be disinfected using a chemical disinfection system only.

See ‘WARNINGS’ for information on the relationship between wearing schedule and corneal complications.

CONTRAINDICATIONS

DO NOT USE the **Menicon Z™ (tisilfocon A)** contact lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior segment of the eye
- Any eye disease, injury, or abnormality (other than irregular corneal conditions as described in ‘INDICATIONS’) that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes), except when using the scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and contact lens
- Corneal hypoesthesia (reduced corneal sensitivity), except when using the scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and contact lens and acts as a protective barrier for the cornea
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues that may be induced or exaggerated by wearing contact lenses and/or using contact lens solutions
- Allergy to any ingredient, such as mercury or thimerosal, in the solution which is to be used for the care of the **Menicon Z™ (tisilfocon A)** contact lens
- Any active corneal infection
- If eyes become red or irritated.
- Incomplete corneal healing following eye surgery

WARNINGS

Patients should be advised of the following warnings pertaining to wearing contact lenses:

- Problems with contact lenses and lens care products could result in **serious injury** to the eyes. It is essential that patients follow the directions of the eye care professional or practitioner and all instructions on the labels for proper use of contact lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear contact lenses (such as lenses for irregular corneas, including keratoconus) are not intended for overnight wear, and patients should be instructed not to wear contact lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions increases when daily wear contact lenses are worn overnight.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when contact lenses are worn overnight or while sleeping.^{1,2}
- If a patient experiences **eye discomfort**, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove the contact lenses** and promptly consult the eye care professional or practitioner.
- UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. The contact lens users should continue to use their protective UV-absorbing eyewear as directed.**
- Never use tap water for the care of the contact lenses and lens cases.
- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If contact lenses have been submersed in water such as when swimming in pools, lakes or oceans, the user should thoroughly clean and disinfect the contact lenses before wearing them again. Ask the eye care professional or practitioner for recommendations about wearing contact lenses during any activity involving water.

- CLAO Journal, January 1996; Volume 22, Number 1, pp. 30-37
- New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

PRECAUTIONS

NON-STERILE. ALWAYS CLEAN AND DISINFECT THE CONTACT LENSES PRIOR TO USE.

- Special Precautions for Eye Care Professional or Practitioner:
- Due to the small number of patients enrolled in clinical investigation of contact lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting appropriate contact lenses and wearing schedule for a patient, the eye care professional or practitioner should consider all lens characteristics 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 eyes should be carefully monitored by the prescribing eye care professional or practitioner.

- The following patients may experience a higher rate of adverse reactions associated with wearing contact lenses:
 - Patients with a history of acute inflammatory reactions to wearing contact lenses.
 - Patients with a history of giant papillary conjunctivitis associated with wearing contact lenses.
 - Patients with a history of ocular allergies that may need to temporarily discontinue wearing contact lenses during certain times of the year.
 - Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule, or follow-up visit schedule.
 - Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.
 - Patients who are unable or unwilling to adhere to a recommended care regimen, or who are unable to put in and remove contact lenses, should not be provided with the contact lenses.
- Eye care professional or practitioner should instruct patients to remove contact lenses immediately if the eyes become red or irritated.
- The use of fluorescein is contraindicated in those people who have a known hypersensitivity to any component.
- The presence of the UV absorber in the **Menicon Z™ (tisilfocon A)** contact lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the **Menicon Z™ (tisilfocon A)** Professional Fitting and Information Guide for detailed instructions.)
- Follow-up visits are necessary to assure the continuing health of patient’s eyes. Patients should be instructed as to a recommended follow-up schedule.

- Aphakic and other post-surgical patients should not wear the **Menicon Z™ (tisilfocon A)** contact lens until the determination is made that the eye has healed completely.
- The contact lenses are shipped immersed in a solution containing 0.00010% polyhexamethylene biguanide hydrochloride as a preservative in foil-sealed individual plastic containers. If the foil-sealed plastic container has missing solution or is dry, return the product to the supplier according to their return policies.

- If a patient is sensitive to any ingredient in the shipping solution, the contact lenses should be removed from the foil-sealed plastic containers upon receipt, rinsed with fresh saline solution, cleaned with a cleaner and put in another prescribed disinfecting solution prior to dispensing the contact lenses. Follow the manufacturer’s instructions on the disinfecting solution label.
- 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.
- It is advised that wound healing and corneal curvature are stable prior to putting in the **Menicon Z™ (tisilfocon A)** contact lens for post-surgical or other compromised corneas.

Eye care professional or practitioner should carefully instruct patients about the following care regimen and safety precautions. It is strongly recommended that patients be provided with a copy of the Patient Instructions for the **Menicon Z™ (tisilfocon A)** Rigid Gas Permeable contact lens available from Menicon and understand the contents prior to dispensing the contact lenses.

Handling Precautions:

- Always wash and rinse hands before handling contact lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the contact lenses. It is best to put in contact lenses before putting on makeup. Water-based cosmetics are less likely to damage contact lenses than oil-based products.
- Before leaving the office of the eye care professional or practitioner, the patient should be able to promptly remove contact lenses or should have someone else available who can remove the contact lenses for the patient.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the contact lenses may occur, causing distorted vision and/or injury to the eyes.
- Always handle contact lenses gently and avoid dropping them on hard surfaces.
- Do not touch contact lenses with fingernails.
- Carefully follow the handling, putting-in, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the **Menicon Z™ (tisilfocon A)** contact lens and those prescribed by the eye care professional or practitioner.
- Never use tweezers or other tools to remove the contact lenses from the plastic container or lens case unless specifically indicated for that use.

Solution Precautions:

- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.

- Sterile non-preserved solutions, when used, should be discarded after the time specified in the directions on the label.
- Always keep the contact lenses completely immersed in the recommended storage solution when the contact lenses are not in use. Prolonged periods of drying may reduce the ability of the lens surface to return to a wettable state.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting contact lenses.
- Different solutions cannot always be used together, and not all solutions are safe for use with all contact lenses. Use only recommended solutions.
- Do not heat the cleaning, wetting, and/or soaking solution and contact lenses. Keep them away from extreme heat.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the contact lenses.

Lens Wearing Precautions:

- Never wear contact lenses beyond the period recommended by the eye care professional or practitioner.
- If the contact lenses stick (stop moving) on the eyes, follow the recommended directions in 'CARE FOR A STICKING (NON-MOVING) LENS'. The contact lenses should move freely on the eyes for the continued health of the eyes. If non-movement of the contact lenses continue, the patient should be instructed to immediately consult the eye care professional or practitioner.
- Avoid all harmful or irritating vapors and fumes while wearing contact lenses.
- If aerosol products such as hair spray are used while wearing contact lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions:

- Lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with the sterile contact lens solution recommended by the lens case manufacturer (never use tap water), and allowed to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens manufacturer or the eye care professional or practitioner.

Topics to Discuss with the Patient:

- Follow-up visits are necessary to assure the continuing health of patient's eyes. Patients should be instructed as to recommended follow-up schedule.
- Patients should be advised about wearing contact lenses during water activities and other sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Always consult the eye care professional or practitioner before using any medicine in the eyes.
- Certain medications may cause dryness of the eyes, increased lens awareness, lens intolerance, blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, oral contraceptives and motion sickness medications. Caution patients using such medications accordingly and prescribe proper remedial measures.

Who Should Know That the Patient is Wearing Contact Lenses:

- Patients should inform the doctor (health care professional) of being a contact lens wearer.
- Patients should always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require not to wear contact lenses.

ADVERSE REACTIONS

- Eye stinging, burning, itching, or any other pain in the eyes
- Less comfort than when the contact lenses were first put in the eyes
- Continuous foreign body or scratching sensation
- Excessive tearing, unusual eye secretions, redness, reduced visual acuity, blurred vision, rainbows, halos, photophobia, or dry eyes

If any of the above problems occur, the patient should be instructed to:

- **Immediately remove the contact lenses.**
- If the discomfort or problem stops, look closely at the contact lenses. If the contact lenses are in any way damaged, do not put them back in the eyes. Put the contact lenses in a lens case and consult the eye care professional or practitioner. If the contact lenses have dirt, an eyelash, or other foreign body on them, or the problem stops and the contact lenses appear undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses, then put them in again. If the problem continues after putting in the contact lenses, the patient should **immediately remove the contact lenses and consult the eye care professional or practitioner.**

If the above symptoms continue after removal of the contact lenses, upon putting in the contact lenses again, or upon putting in new contact lenses, the patient **should immediately remove the contact lenses and consult the eye care professional or practitioner, or physician**, who must determine the need for examination, treatment or referral without delay (see 'Important Treatment Information for Adverse Reactions'). A serious condition such as infection,

corneal ulcer, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

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

Important Treatment Information for Adverse Reactions:

Sight-threatening ocular complications associated with wearing contact lenses can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. To prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical , treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately, and the lens and lens care products should be retained for analysis and culturing.

PREPARATION FOR PUTTING IN THE CONTACT LENSES

The **Menicon Z™ (tisilfocon A)** contact lens should be thoroughly cleaned with the recommended cleaning solution and disinfected/hydrated in the desired soaking/conditioning solution according to the directions on the label prior to putting in the contact lenses to insure maximum surface wettability.

PUTTING IN THE CONTACT LENSES

Conventional methods of putting in contact lenses for regular corneas apply to the **Menicon Z™ (tisilfocon A)** contact lens. Special methods are needed for irregular corneas. For a detailed description of the methods, refer to the **Menicon Z™ (tisilfocon A)** Professional Fitting and Information Guide which are available from:

SynergEyes, Inc.
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Carlsbad, CA 92008
Tel.: 1-760-476- 9410
FAX: 1-760-476- 9340
www.synergeyes.com

WEARING SCHEDULE

THE WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PROFESSIONAL OR PRACTITIONER.

Patients tend to overwear contact lenses initially. The eye care professional or practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care professional or practitioner, are also extremely important.

For the management of irregular corneal conditions, close supervision by the eye care professional or practitioner is necessary. The eye care professional or practitioner should determine the appropriate wearing time and provide specific instructions to the patient regarding lens care, and putting-in and removal of the contact lenses.

Warning:

Patients wearing the **Menicon Z™ (tisilfocon A)** contact lens for the management of keratoconus or other types of irregular cornea should NOT wear the contact lenses overnight or sleep in them. For these patients, wearing contact lenses while asleep can cause serious adverse reactions or loss of vision. It is essential that the wearing schedule should be individually determined by the eye care professional or practitioner.

The **Menicon Z™ (tisilfocon A)** contact lens is indicated for daily wear. The suggested maximum wearing time for the contact lenses is:

During Waking Hours*

| DAY | 1 | 2 | 3 | 4 | 5 | 6 and after |
|-------|-----|------|------|-------|---------------------|------------------|
| HOURS | 4-8 | 6-10 | 8-14 | 10-15 | 12-all waking hours | All waking hours |

* If the contact lenses continue to be well tolerated.

The contact lenses should be removed at the end of each day for cleaning and disinfecting (according to lens care system instructions).

LENS CARE DIRECTIONS

NEVER USE ABRASIVE SURFACTANT CLEANERS SUCH AS BOSTON®, BOSTON ADVANCE®, OPTI-FREE® AND OPTI-SOAK® WITH THIS CONTACT LENS.

Eye care professional or practitioner 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:

Basic Instructions:

- Always wash and rinse hands before handling contact lenses.
- Always use **fresh unexpired** lens care solutions.
- Use the recommended chemical (not heat) system of lens care and carefully follow instructions on the solution label. Different solutions cannot always be used together, and not all solutions are safe for use with all contact lenses. **Do not alternate or mix lens care systems unless indicated on the product instructions.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting contact lenses. Do not put lenses in the mouth.
- The 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 lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme (as recommended by the eye care professional or practitioner) and disinfect contact lenses according to the schedule prescribed by the eye care professional or practitioner. The use of an enzyme or any cleaning solution **does not substitute for disinfection.**
- The lens care products listed below are recommended by Menicon for use with the **Menicon Z™ (tisilfocon A)** contact lens. Refer to the package inserts for the products that may be used with the contact lenses. The eye care professional or practitioner may recommend alternate solutions that are appropriate for use with the contact lenses. Care should be taken not to mix solutions from different companies and/or care systems unless specifically instructed to do so by the eye care professional or practitioner.

Recommended Care System:

| Solution Purpose | Lens Care System Chemical (not heat) disinfection |
|---------------------------------|--|
| Cleaning | Menicon Unique pH® Multi-Purpose Solution |
| Rinsing | Menicon Unique pH® Multi-Purpose Solution, LacriPure or solutions recommended by the eye care professional or practitioner |
| Disinfection/Storage | Menicon Unique pH® Multi-Purpose Solution |
| Lubrication/Rewetting | Solutions recommended by the eye care professional or practitioner |
| Periodic Protein Cleaning | Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses |
| Use with Scleral Contact Lenses | Sterile non-preserved solution (e.g., LacriPure) or solutions recommended by the eye care professional or practitioner |

- Some solutions may have more than one function, which will be indicated on the label. Read the label of the solution, and follow the instructions.
- Always clean the same contact lens first to avoid mix-ups with a recommended cleaning solution. Rinse the contact lens thoroughly with recommended solution to remove the cleaning solution, mucus, and film from the lens surface, and put the contact lens into the correct chamber of the lens case. Then repeat the procedure for the other lens.
- After cleaning, disinfect contact lenses using the system recommended by the manufacturer and/or the eye care professional or practitioner.
- To store contact lenses, disinfect and store them in a closed/unopened lens case until ready to wear. If contact lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care professional or practitioner for information on storage of the contact lenses.
- After removing contact lenses from a lens case, empty and rinse the lens case with sterile contact lens solutions recommended by the lens case manufacturer (never use tap water); then allow the lens case to air dry. When the lens case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or the eye care professional or practitioner.
- The eye care professional or practitioner may recommend a **lubricating/rewetting** solution, which can be used to wet (lubricate) contact lenses while they are being worn to make them more comfortable.
- The **Menicon Z™ (tisilfocon A)** contact lens cannot be heat (thermally) disinfected.

Chemical (Not Heat) Disinfection:

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse the contact lenses with a recommended rinsing solution.
- To disinfect the contact lenses after cleaning, carefully follow

the instructions for the disinfecting solution in the care regimen recommended by the lens manufacturer or the eye care professional or practitioner.

- Thoroughly rinse contact lenses with a recommended fresh saline solution before wearing, or follow the instructions on the disinfection solution label.
- Do not heat the disinfection solution and contact lenses.
- Store the contact lenses in an unopened lens case until ready to wear.
- Contact lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse with fresh sterile saline solution (or follow the instructions on the disinfection solution label) prior to putting in the contact lenses should reduce the potential for irritation.

Lens Deposits and Enzymatic Cleaning:

Enzyme cleaning may be recommended by the eye care professional or practitioner. Enzyme cleaning removes protein deposits on contact lenses. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the contact lenses and eyes. If these deposits are not removed, they can damage the contact lenses and cause irritation to the eyes. The eye care professional or practitioner should recommend a schedule that is right for the patient.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions on the enzymatic cleaning solution label.

CARE FOR A STICKING (NON-MOVING) LENS

If the contact lenses stick (stop moving) on the eyes, the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eyes and wait until the lenses begin to move freely on the eyes before removing them. If non-movement of the contact lenses continue for more than 10 minutes, the patient should **immediately** consult the eye care professional or 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 THE EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE THE CONTACT LENSES PROMPTLY. CONSULT THE EYE CARE PROFESSIONAL OR PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

The non-sterile **Menicon Z™ (tisilfocon A)** contact lens is shipped immersed in a solution containing 0.00010% polyhexamethylene biguanide hydrochloride as a preservative in foil-sealed individual plastic containers. If the patient is sensitive to any ingredient in the shipping solution, the contact lenses should be removed from the foil-sealed plastic containers upon receipt, rinsed with fresh saline solution, cleaned with a cleaner and put in another prescribed disinfecting solution prior to dispensing the contact lenses. Follow the manufacturer's instructions on the disinfecting solution label.

Dry shipping of the contact lenses are available upon request.

The foil-sealed plastic container, packing slip or invoice is marked with the information for base curve, diopter power, diameter, center thickness, color, a UV-absorber symbol, serial No., expiration date and other required parameters for the design.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and reactions observed in patients wearing the **Menicon Z™ (tisilfocon A)** contact lens should be reported to:

SynergEyes, Inc.
2232 Rutherford Rd
Carlsbad, CA 92008
Tel.: 1-760-476- 9410
FAX: 1-760-476- 9340
www.synergeyes.com

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Menicon Z™

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