



Menicon Z™ (tisilfocon A)

Rigid Gas Permeable Contact Lens

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Phone: +31 591 610 640
www.nkl.nl

FDA registration number: 3003357577

Product name List

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

| Product Name | Abbreviation | Single Vision | Multi-focal | Toric Back | Toric Front |
|--|--------------------------------|---------------|-------------|------------|-------------|
| SynergEyes GP | SynergEyes GP | X | | | |
| SynergEyes GP Front toric | SynergEyes GP FtrTor | | | | X |
| SynergEyes GP Bitoric | SynergEyes GP Bitor | | | X | X |
| SynergEyes GP Bitoric Extra | SynergEyes GP Bitor Ext | | | X | X |
| SynergEyes GP Progressive D | SynergEyes GP Pro D | | X | | |
| SynergEyes GP Progressive N | SynergEyes GP Pro N | | X | | |
| SynergEyes GP Progressive D Plus | SynergEyes GP Pro D+ | | X | | |
| SynergEyes GP EP | SynergEyes GP EP | | X | | |
| SynergEyes GP Bitoric Extra Progressive | SynergEyes GP Bitor Ext D | | X | X | X |
| SynergEyes GP Bitoric Progressive | SynergEyes GP Bitor Pro D | | X | X | X |
| SynergEyes GP Bitoric Progressive Plus | SynergEyes GP Bitor Pro D+ | | X | X | X |
| SynergEyes GP Bitoric Extra Progressive Plus | SynergEyes GP Bitor Ext Pro D+ | | X | X | X |
| SynergEyes GP II | SynergEyes GP II | X | | | |
| SynergEyes GP II Bitoric | SynergEyes GP II Bitor | | | X | X |
| SynergEyes GP II Bitoric Extra | SynergEyes GP II Bitor Ext | | | X | X |
| SynergEyes GP II EP | SynergEyes GP II EP | | X | | |
| SynergEyes GP II Progressive D | SynergEyes GP II Pro D | | X | | |
| SynergEyes GP II Progressive N | SynergEyes GP II Pro N | | X | | |
| SynergEyes GP II Bitoric Progressive | SynergEyes GP II Bitor Pro D | | X | X | X |
| SynergEyes GP II Bitoric EP | SynergEyes GP II Bitor EP | | X | X | X |

| Product Name | Abbreviation | Single Vision | Multi-focal | Toric Back | Toric Front |
|--|----------------------------------|----------------------|--------------------|-------------------|--------------------|
| SynergEyes GP II Bitoric Extra Progressive | SynergEyes GP II Bitor Ext Pro D | | X | X | X |
| SynergEyes GP II Bitoric Extra EP | SynergEyes GP II Bitor Ext EP | | X | X | X |
| SynergEyes GP II Progressive D Plus | SynergEyes GP II Pro D+ | | X | | |
| SynergEyes VS - Sphere | SynergEyes VS Sph | X | | | |
| SynergEyes VS | SynergEyes VS | | | X | X |
| SynergEyes VS XL - Sphere | SynergEyes VS XL Sph | X | | | |
| SynergEyes VS XL | SynergEyes VS XL | | | X | X |
| SynergEyes VS XL QT | SynergEyes VS XL QT | | | X | X |

FDA registration

Establishment Registration & Device Listing

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Establishment:
NKL Contactlenzen
Waanderweg 6
Emmen Drenthe, NETHERLANDS 7812 HZ
Registration Number: 3003357577
FEI Number: 3003357577
Status: Active
Date Of Registration Status: 2017

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* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set.

Authorization letter by Menicon Co.



Menicon Co., Ltd.

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DECLARATION

This is to certify that NKL Contactlenzen of Waanderweg 6 7812 HZ Emmen, The Netherland has been evaluated in accordance with, and found to conform to, all provisions of protocol for adding Lens Finishing Laboratories (K000133).

Menicon Co., Ltd.

3-21-19 Aoi, Naka-ku

Nagoya 460-0006

JAPAN

By: Tetsuya Miyachi Date: Dec. 20, 2016

Tetsuya Miyachi

General Manager of Quality Assurance

Management Representative

Menicon Co., Ltd.

PACKAGE INSERT

FOR DAILY WEAR CORNEAL AND SEMI-SCLERAL LENSES

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

CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a licensed eye care professional.

Menicon Z™ (tisilfocon A)

Rigid Gas Permeable Contact Lenses

Spherical and Aspheric Lenses for Myopia and Hyperopia

Toric Lenses to Correct Astigmatism

Lenses for the Management of Irregular Corneas

Multifocal Lenses for Presbyopia

in Aphakic and Non-Aphakic Persons

DESCRIPTION:

The Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens is available as a spherical, aspheric, prism ballast toric or multifocal design.

Semi-scleral and scleral lenses are available for daily wear only.

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 lens is available in a clear and a light blue tint. The 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 Lenses:

- Diameter 7.0 to 21.0mm
- Center Thickness 0.08 to 0.50mm
- Base Curve 4.00 to 11.5mm
- Powers -25.00 to +25.00D (in 0.25D steps)

Toric lenses:

- Diameter 7.0 to 21.0mm
- Center Thickness 0.08 to 0.50mm
- Base Curve 7.30 to 8.50mm
- Sphere Powers -10.00 to +8.00D (in 0.25D steps)
- Cylinder Powers -0.50 to -5.00D (in 0.25D steps)
- Prism Ballast 0.75 to 2.00D (in 0.25D steps)
- Truncation Height 0.0 to 1.0mm (in 0.1mm steps)

Multifocal Lens (Centered, Decentered, Crescent):

- Diameter 8.8 to 21.0mm
- Center Thickness 0.08 to 0.65mm
- Base Curve 7.00 to 9.00mm
- Sphere Power -13.00 to +5.00D
- Add Power +1.00 to +3.00D

The physical/optical properties of the lens are:

- Specific Gravity: 1.20
- Refractive Index: n_{25D} 1.436± 0.001
- Surface Character: Hydrophobic

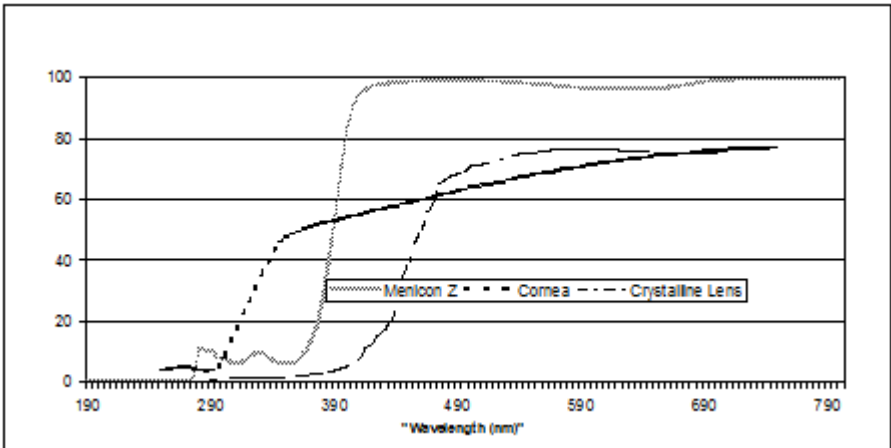
- Wetting Angle: 24 degrees (after soaking)
- Light Transmittance:
 - Visible region >95% (380 nm – 780 nm)
 - Ultraviolet region <6% (210 nm – 380 nm)
 - (sample thickness 0.08mm)
- Water Absorption: Less than 0.5% by weight
- Oxygen Permeability:
 - 163×10^{-11} (cm²/sec)(mL O₂/(mL x mmHg)) Dk*
 - 189×10^{-11} **
 - 250×10^{-11} ***

* Method for determination of oxygen permeability: ISO/DIS 9913.1 1994. Optics and optical instruments - Contact lenses - Part 1: Determination of oxygen permeability and transmissibility with the Fatt method. (PHEMA Standard)

** Measurement of Dk by Fatt, Polarographic method. (PHEMA Standard)

*** Measurement of Dk by the Hamano Polarographic method. (Teflon Standard)

WAVELENGTH nm



Menicon Z™ (tisilfocon A) Contact Lens - Spectral transmittance curve for Menicon Z™ (tisilfocon A) Contact Lens - D & C Green No. 6 and UV absorbing agent (sample thickness Menicon Z™ (tisilfocon A) lens polymer plate = 0.08mm, representing the thinnest marketed version of the 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 for more information.

TRADE NAME LIST

All products in this list are manufactured of Menicon Z™ (tisilfocon A). The information in this booklet 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 |

| Product Name | Abbreviation |
|--|----------------------------------|
| 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 XL - Sphere | SynergEyes VS XL Sph |
| SynergEyes VS XL | SynergEyes VS XL |
| SynergEyes VS XL QT | SynergEyes VS XL QT |

ACTIONS

The Menicon Z™ (tisilfocon A) Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina. The Menicon Z semi-scleral and scleral contact lens when placed 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 lens and the 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 (USES):

The Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens is available as a spherical, aspheric, prism ballast toric or multifocal design and prism ballast multifocal lenses are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

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

The lenses may be prescribed for daily wear in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery.

The lens may be disinfected using a chemical disinfection system only.

See **WARNINGS** for information about the relationship between wearing schedule and corneal complications.

CONTRAINDICATIONS (REASONS NOT TO USE):

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 the "Indications" Section) that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes), except when using a semi-scleral or scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and the contact lens
- Corneal hypoesthesia (reduced corneal sensitivity), except when using a semi-scleral or scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and the 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 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 the Menicon Z™ (tisilfocon A) Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated
- Incomplete healing following eye surgery

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 professional'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.
- Daily wear lenses (such as lenses for irregular corneas, including keratoconus) 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 daily wear lenses are worn overnight.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when 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 lenses and promptly contact his or her eye care professional.
- 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. Persons should continue to use their protective UV-absorbing eyewear as directed.
- Never use tap water.
- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water such as when swimming in pools, lakes or oceans, you should thoroughly clean and disinfect them before insertion. Ask your eye care professional for recommendations about wearing your lenses during any activity involving water.

¹CLAO Journal, January 1996; Volume 22, Number 1, pp. 30-37

²New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

PRECAUTIONS:

CAUTION: non-sterile. Always clean and disinfect lenses prior to use.

Special Precautions for Eye care Professionals:

- 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 and wear schedule for a patient, the eye care professional 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 eye should be carefully monitored by the prescribing eye care professional.
- The following patients may experience a higher rate of adverse effects associated with contact lens wear:
 - ◇ Patients with a history of acute inflammatory reactions to contact lens wear.
 - ◇ Patients with a history of giant papillary conjunctivitis associated with contact lens wear.
 - ◇ Patients with a history of ocular allergies may need to temporarily discontinue lens wear 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 unwilling or unable to adhere to a recommended care regimen, or who are unable to insert and remove lenses, should not be provided with them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The use of fluorescein is contraindicated in those persons who have a known hypersensitivity to any component.
- The presence of the ultraviolet (UV) light absorber in the Menicon Z™ (tisilfocon A) Contact Lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)

- 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.
- Aphakic and other post-surgical persons should not be fitted with Menicon Z™ (tisilfocon A) Contact Lenses until the determination is made that the eye has healed completely.
- Lenses are shipped in a plastic container immersed in Menicon Unique pH® Multi-Purpose Solution. If the plastic container has missing solution or is dry, return the product to your supplier according to their return policies.
- If continual wet storage of wet shipped contact lenses is preferred, Menicon Unique pH® Multi-Purpose Solution should be changed every 30 days from the hydration date.
- If the patient is sensitive to any ingredient in the shipping solution, the lens should be removed from the vial upon receipt, rinsed with fresh saline solution, cleaned with a cleaner and placed in another prescribed disinfecting solution prior to dispensing. 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 fitting Menicon Z™ lenses for post-surgical or other compromised corneas.

Eye care professionals 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 its contents prior to dispensing the lenses.

Handling Precautions:

- 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-based cosmetics are less likely to damage lenses than oil-based products.
 - Before leaving the eye care professional'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.
- 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.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Do not touch the lens with fingernails.

- Carefully follow the handling, insertion, 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.
- Never use tweezers or other tools to remove lenses from the lens container 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 unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). 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 lenses.
- 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 cleaning, wetting, and/or soaking solution and lenses. Keep away from extreme heat.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the Menicon Z™ (tisilfocon A) Contact Lenses.

Lens Wearing Precautions:

- Never wear lenses beyond the period recommended by the eye care professional.
- If the lens sticks (stops moving) on the eye, follow the recommended directions in **Care for a Sticking (Non-Moving) Lens**. 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 professional.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions:

- Contact 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 your eye care professional.

Topics to Discuss with the Patient:

- 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.
- Patients should be advised about wearing 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 contact the eye care professional before using any medicine in the eyes.
- Certain medications may cause dryness of the eye, 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) about 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 that the patient not wear contact lenses.

ADVERSE REACTIONS:

- Eyes stinging, burning, itching (irritation) or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal 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, 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 professional. 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 professional.**

- If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient **should immediately remove the lenses and contact his or her eye care professional** 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 effect may be due to the original condition or may be due to the effects of wearing a contact lens. There is a possibility that the existing condition might become worse when a lens is used on an eye with an irregular corneal condition. The patient should be instructed to avoid serious eye damage by contacting the eye care professional IMMEDIATELY if there is an increase in symptoms while wearing the lens.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear 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. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, 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 retained for analysis and culturing.

PREPARING A RGP LENS FOR FITTING

Menicon Z™ (tisilfocon A) Contact Lenses should be thoroughly cleaned with the recommended cleaning solution and disinfected/hydrated in the desired

soaking/conditioning solution according to the labeled directions for use prior to placement on the eye to insure maximum surface wettability.

FITTING:

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

SynergEyes Inc.
5927 Priestly Drive, Suite 210
Carlsbad CA 92008
Tel.: (760) 476- 9410; FAX: (760) 476- 9340
www.synergeyes.com

WEARING SCHEDULE:

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

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

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

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

*During Waking Hours**

| Day | Hours |
|-----|-------|
| 1 | 4-8 |
| 2 | 6-10 |

- 3 8-14
- 4 10-15
- 5 12-all waking hours
- 6 and after - all waking hours

* If the lenses continue to be well tolerated.

Lenses should be removed daily for cleaning and disinfecting (according to lens care system instructions) before wearing.

LENS CARE DIRECTIONS:

Note: ABRASIVE SURFACTANT CLEANERS SUCH AS BOSTON®, BOSTON ADVANCE®, OPTI-FREE® AND OPTI-SOAK® SHOULD NOT BE USED.

Eye care professionals 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. 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 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.
- Always remove, clean, rinse, enzyme (as recommended by the eye care professional) and disinfect lenses according to the schedule prescribed by the eye care professional. 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. See Package Insert for other products that may be used with this lens. Eye care professionals may recommend alternate solutions that are appropriate for the patient's use with his or her lens. 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.

RECOMMENDED CARE SYSTEM:

LENS CARE TABLE

| Solution Purpose | Lens Care System |
|--|---|
| | Chemical (not heat) disinfection |
| Cleaning | MeniCare GP Cleaning, Disinfecting and Storage Solution, or Menicon Unique pH [®] Multi-Purpose Solution |
| Rinsing | Menicon Unique pH [®] Multi-Purpose Solution, LacriPure or other solution as recommended by your eye care professional |
| Disinfection/Storage | MeniCare GP Cleaning, Disinfecting and Storage Solution, or Menicon Unique pH [®] Multi-Purpose Solution |
| Lubrication/Rewetting | MeniCare GP Wetting / Rewetting Drop (WRW) |
| Periodic Protein Cleaning | Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses |
| Insertion of semi-scleral & scleral lenses | Sterile Non-preserved Solution (e.g., LacriPure) or as recommended by your eye care professional |

- **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) with a recommended cleaning solution. Rinse the lens thoroughly with recommended 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 professional.
- 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 professional for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with sterile contact lens solution as recommended by the lens case manufacturer (never use tap water); 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 professional.
- Eye care professionals may recommend a **lubricating/rewetting** solution, which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

- Menicon Z™ (tisilfocon A) 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, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eye care professional.
- Thoroughly rinse lenses with a fresh saline 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.
- **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 (or follow the instructions on the disinfection solution labeling) 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 eye care professional. 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. Your eye care professional will recommend a schedule that is right for you.

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

CARE FOR A STICKING (NON-MOVING) LENS:

If the lens sticks (stops moving), the patient should be instructed to apply a few 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 none movement of the lens continues after 10 minutes, the patient should **immediately** consult the eye care professional.

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 THEN REMOVE LENSES PROMPTLY. CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

Each Menicon Z™ (tisilfocon A) Contact Lens is shipped non-sterile immersed in Menicon Unique-pH® Multi-Purpose Solution (0.0011% polyquaternium-1 and 0.01% edetate disodium as preservatives) in an individual plastic container. If the patient is sensitive to any ingredient in the solution, the lens should be removed from the plastic container upon receipt, rinsed with fresh saline solution, cleaned with a cleaner and placed in another prescribed disinfecting solution prior to dispensing. Follow the manufacturer's instructions on the disinfecting solution label.

Dry shipped lenses are available upon request.

The plastic container, packing slip or invoice is marked with the information for base curve, diopter power, diameter, center thickness, color, UV-absorber, Serial No., hydration date and other required parameters specified by the design.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing Menicon Z™ (tisilfocon A) Contact Lenses should be reported to:

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