PATIENT INSTRUCTIONS

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

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

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INTRODUCTION

This document describes how to safely use the Menicon Z™ (tisilfocon A) contact lens. Please read carefully and keep this information for future use.

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 Menicon Z™ (tisilfocon A) contact lens is available in a clear and a light blue tint. Also, a UV absorber (Benzotriazol) is added as an additive during the manufacturing process.

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 XL - Sphere	SynergEyes VS XL Sph		
SynergEyes VS XL	SynergEyes VS XL		
SynergEyes VS XL QT	SynergEyes VS XL QT		

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

Contact lenses larger than 12.0 mm in diameters are available for daily wear only.

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.

The contact lenses should be removed at the end of each day for cleaning and disinfecting (as prescribed by the eye care professional or

DO NOT WEAR THE MENICON Z™ (TISILFOCON A) CONTACT

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

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

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 seament of the eve
- Any eye disease, injury, or abnormality (other than irregular corneal conditions as described in 'INDICATIONS') that affects the cornea, conjunctiva, or evelids
- 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 you 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 should not be worn 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
- If you experience **eye discomfort**, excessive tearing, vision changes, or redness of the eye, you should immediately remove the contact lenses and promptly consult the eye care ofessional 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 eve and surrounding area. You should continue to use your 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, you 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),

PRECAUTIONS

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

- 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, you should be able to promptly remove contact lenses or should have someone else available who can remove the contact lenses for you.
- Do not touch contact lenses with 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
- 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 this document 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

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 eve 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, you should immediately consult the eve 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 Eye Care Professional or Practitioner:

- Follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow un schedule.
- You 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. Always inform the eye care professional or practitioner if you experience any problems with the contact lenses while using such medications.

Who Should Know That You are Wearing Contact Lenses:

- You should inform your doctor (health care professional) of being a contact lens wearer.
- You should always inform your 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
- 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, you should:

- 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, you should thoroughly clean, rinse, and disinfect the contact lenses, then put them in again. If the problem continues after putting in the contact lenses, you 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, you 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. You should 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 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 eve when examined, the lens should be removed immediately, and the lens and lens care products should be retained for analysis and

PROCEDURES FOR HANDLING THE CONTACT LENSES

1. Preparation for Putting in the Contact Lenses:

It is essential that you learn and use appropriate hygienic methods in the care and handling of the contact lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle contact lenses.

- Always wash hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching contact lenses. Proper hand washing can help to prevent eye infections.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling contact lenses, since these substances may come into contact with contact lenses and interfere with
- successful wearing. Handle contact lenses with fingertips, and avoid contact with fingernails. It is helpful to keep your fingernails short and smooth. Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

Handling the Contact Lenses

- Always handle the left and right contact lenses in the same sequence to avoid mixing up the contact lenses.
- Remove the contact lens from the lens case and examine it to be sure that it is moist, clean, clear, and free of any nicks or cracks.

Putting in the Contact Lenses

Always put in the left and right contact lenses in the same sequence to avoid mixing up the contact lenses. Although the eye care professional or practitioner will instruct a method that is most suitable for you, the following is a standard procedure for putting in and removing contact lenses.

If you are wearing large diameter, scleral contact lenses that cover your entire cornea, see 'Putting in Scleral Contact Lenses' for

- putting in the contact lenses.

 1. Place the contact lens on the tip of the forefinger of your dominant hand with the concave side facing up.
- 2. Hold your eyelids wide apart with the thumb and index finge of the other hand.
- 3. Slowly bring the contact lens up to your eye while looking straight ahead, and gently put the lens on the cornea.

 • Do not press the contact lens against your eye.
- 4. Release the eyelids slowly and blink gently. 5. Check your vision of the eye to ensure the contact lens is in place before moving around to avoid accidental loss of a misplaced lens.
- 6. Repeat this procedure for the other lens.

IF IT IS EASIER, YOU CAN SWITCH HANDS.

There are other methods for putting in the contact lenses. If the above method is difficult for you, the eve care professional or practitioner will provide you with an alternate method.

Putting in Scleral Contact Lenses:

- Place the contact lens between the index and middle fingers with the concave side facing up.
- Completely fill the contact lens with the solution recommended by the eye care professional or practitioner.

 • This is very important to reduce the risk of unwanted air
- bubbles under the contact lens. With your head facing downward, put the solution-filled contact
- lens in the eye.

provide you with an alternate method.

Repeat this procedure for the other lens. There are other methods for putting in the contact lenses. If the above method is difficult for you, the eye care professional or practitioner will

Note: If your vision is blurred after putting in the contact lenses, check for the following:

- If the contact lenses are not centered on the eyes, see 'Centering the Contact Lenses'. If the contact lenses are centered, remove the lenses (see
- 'Removing the Contact Lenses') and check for the following:
- ♦ Cosmetics or oils are on the lenses. If so, clean, rinse, disinfect and put the lenses in the eyes again.
- The lenses are on the wrong eyes. ♦ The lenses may be cracked, broken or damaged. If so, do not put them back in the eyes.

If your vision is still blurred after clearing the problems mentioned above, remove the contact lenses and consult the eye care professional or practitioner.

4. Centering the Contact Lenses:

Contact lenses on the cornea will sometimes be displaced onto the white part of the eyes during wearing. This can also occur when putting in or removing contact lenses if the correct techniques are not performed properly. To center a contact lens on the eye, follow the procedure below.

- Locate the contact lens using a mirror.
- Place your index finger on the edge of your eyelid, gently push the lens toward the center of the eye
 - Take care not to push too hard.

5. Removing the Contact Lenses:

Always remove the same contact lens first. For removing scleral contact lenses, you may use a contact lens suction cup in the following method.

- Wash, rinse, and dry hands thoroughly.
- Make sure that the contact lens is in place using a mirror.
- Open your eyes as wide as possible, place the index finger at the outside corner of your eye, and look down into the palm of the

- other hand or the center of a soft cloth placed on a flat surface. While keeping your eyes wide open and the lens centered between the evelids, gently pull the outside corner of your eve
- Blink once quickly.

The contact lens should fall out onto the hand or cloth.

- Do not pry the lens loose or use a fingernail to remove it. If the lens does not come out, open your eyes wide and try the succeeding procedure again.
- Remove the other lens with the same procedure
- Perform the lens care procedures described in 'LENS CARE DIRECTIONS'.

If the above method is difficult for you, the eye care professional or practitioner will provide you with an alternate method

LENS CARE DIRECTIONS

Basic Instructions:For continued safe and comfortable wearing of contact lenses, the contact lenses should be cleaned, rinsed, and disinfected each time they are removed using the care regimen recommended by the eve care professional or practitioner. **Cleaning and rinsing** are necessary to remove mucus, secretions, films, or deposits accumulated during wearing. It is ideal that the contact lenses are cleaned immediately after removing them. Failure to clean and rinse prior to disinfecting may result in incomplete lens disinfection. Disinfecting is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow a recommended care regimen may result in development of serious ocular complications as described in 'WARNINGS'. If you will not or cannot adhere to a recommended care regimen, or are unable to put in and remove contact lenses or have someone available to put in and remove the lenses for you, you should not wear contact lenses.

When you first get contact lenses, be sure to put in and remove the lenses while you are in the office of the eye care professional or practitioner. You will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. The eye care professional or practitioner should instruct you about appropriate and adequate procedures and products for use, and provide you with a copy of the Patient Instructions for the Menicon Z™ (tisilfocon A) contact lens.

For safe wearing of contact lenses, you should understand and always

- 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.
- 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. Lens care products provide specific directions for use and important safety information, which you should read and carefully follow

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

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
- 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. Follow the instructions provided on the cleaning solution label.
- After cleaning, disinfect contact lenses using the system recommended by the manufacturer and/or the eye care professional or practitioner. Follow the instructions provided on the disinfection solution label.
- 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, you should consult the package insert or the eye care professional or practitioner for information on storage of the contact lenses.
- Always keep the contact lenses completely immersed in the recommended storage solution when the contact lenses are not in use. If you discontinue wearing the contact lenses, but plan to begin wearing them again after a few weeks, consult the eye care professional or practitioner for a recommendation on how to store the contact lenses.
- After removing contact lenses from a lens case, empty and rinse the lens case with sterile contact lens solutions recom 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 eve care professional or practitioner may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) contact lenses while you are wearing them 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 eve 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
- 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

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 you.

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

LENS CASE CLEANING AND MAINTENANCE

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.

Never add fresh solution to old solution since this can increase the risk of contact lens and lens case contamination and eye infection Lens cases should be replaced at regular intervals as recommended by the lens manufacturer or the eye care professional or practitioner

CARE FOR A STICKING (NON-MOVING) LENS

If the contact lenses stick (stop moving) on the eyes, you should 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, you should immediately consult the eve care professional or practitioner

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you 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.

INSTRUCTIONS FOR THE MONOVISION CONTACT LENS WEARERS

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision correction. The benefit of clear near vision in straight-ahead and upward gazes may be accompanied by a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. Some patients may experience difficulty in adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks during initial adaptation period. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear the contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of wearing the contact lenses. It is recommended that you only drive with the contact lenses if you pass your state driver's license requirements with the contact lenses.
- Some patients will never be fully comfortable with the vision under low levels of illumination, such as driving at night. If this happens, consult the eye care professional or practitioner for having additional contact lenses or glasses prescribed so that

- both eyes are corrected for distance when sharp distance vision
- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses or glasses prescribed. You should discuss your specific visual needs with the eye care professional or practitioner.
- It is important that you follow suggestions of the eye care professional or practitioner for adaptation to monovision correction. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with monovision correction is most appropriately left to the eye care professional or practitioner in conjunction with you, after carefully considering and discussing

INSTRUCTIONS FOR THE PRESBYOPIC PATIENTS (MULTIFOCAL OR MONOVISION CONTACT LENS WEARERS)

- Two common methods of using contact lenses for presbyopic vision correction include multifocal or bifocal contact lens, and monovision correction. Like bifocal, trifocal, or progressive addition glasses, multifocal contact lenses have separate powers for distance and near vision in each lens. This allows the wearer to use both eyes for seeing at all distances. Monovision correction entails the use of standard single vision lenses with a distance powered lens being worn on one eye and a near powered lens on
- You should be aware that as with any type of lens correction, there are advantages and compromises to multifocal or monovision correction. The benefit of clear near vision in straight-ahead and upward gazes may be accompanied by a vision compromise that may reduce visual acuity at certain distances or under certain lighting conditions. Some patients, particularly those wearing monovision contact lenses may experience reduced depth perception. Some patients may experience difficulty in adapting to it. Symptoms, such as mild blurred vision, dizziness headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks during initial adaptation period. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear the contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of wearing the contact lenses. It is recommended that you only drive with the contact lenses if you pass your state driver's license requirements with the contact lenses.
- Some patients will never be fully comfortable with the vision under low levels of illumination, such as driving at night. If this happens, consult the eye care professional or practitioner for having additional contact lenses or glasses prescribed so that both eyes are corrected for distance when sharp distance vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses or glasses prescribed. You should discuss your specific visual needs with the eye care professional or practitioner.
- It is important that you follow suggestions of the eye care professional or practitioner for adaptation to presbyopic vision correction. You should discuss any concerns that you may have
- during and after the adaptation period.
 The decision to be fit with multifocal or monovision correction is most appropriately left to the eye care professional or practitioner in conjunction with you, after carefully considering and discussing

INSTRUCTIONS FOR THE PATIENTS WITH KERATOCONUS. **IRREGULAR CORNEA OR POST-SURGICAL CORNEA**

- The contact lenses are indicated for daily wear only (no overnight wear). You should NOT wear the contact lenses while sleeping. No clinical studies have been done to establish the safety of sleeping in the contact lenses for patients with keratoconus, irregular corneas or post-surgical corneas. Clinical studies have shown that the risk of serious adverse reactions increases when daily wea contact lenses are worn overnight.
 The eye care professional or practitioner should determine the
- appropriate wearing schedule according to your individual needs. It is very important to carefully follow these recommendations. and the instructions of the eye care professional or practitioner regarding lens care, and putting-in and removal of the contact

WEARING AND APPOINTMENT SCHEDULES

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

Patients tend to overwear contact lenses initially. It is important to adhere to the initial maximum wearing schedule established by the eye care professional or practitioner. In no event should your initial maximum wearing schedule exceed the schedule set forth below. Regular checkups, as determined by the eye care professional or practitioner, are also extremely important.

Do not skip visits with the eye care professional or practitioner even if you feel comfortable with the contact lenses. Routine follow-up visits help prevent problems. Only a thorough examination by the eye care professional or practitioner can determine how your eyes are responding to the contact lenses. Early signs of a problem can be detected and treated before you can feel them.

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 you with specific instructions regarding lens care, and putting-in and removal of the contact lenses.

If you wear the **Menicon Z™** (tisilfocon A) contact lens for the management of keratoconus or other types of irregular cornea, you should NOT wear the contact lenses overnight or sleep in them. If

you have keratoconus or another type of irregular corneal condition, 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 of

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	All waking
l					hours	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).

Prescribed Wearing Schedule

Your appointments are on:

Year

Month

Day	wearing time (Hours)	
1		
2		
3		
4		
5		
6 and after		
Appointment Schedule		

Time

Eve Care Professional or Practitioner Information

Minimum Number of Hours for the Contact Lenses to be Worn:

Patient/Eye Care Professional or Practitioner Information:

Day at time of appointment

Name			
Practice Name			
Address			
Phone Number			
Recommended Lens Care Regimen			
Cleaning Solution			
Rinsing Solution			
Disinfecting Solution			
Lubricating Solution			

Use with Scleral Contact Lenses

In the event that you experience any difficulty wearing the contact lenses or you do not understand the instructions given to you, DO NOT WAIT for your next appointment.

TELEPHONE THE EYE CARE PROFESSIONAL OR PRACTITIONER IMMEDIATELY.

Print Date 2018-12-07



LMS0028-02