

# PATIENT INSTRUCTIONS

(FOR DAILY WEAR CORNEAL AND SCLERAL LENSES)

For Menicon Z™ (tisilfocon A)

Rigid Gas Permeable Contact Lens

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

SynergEyes, Inc.  
5927 Priestly Drive, Suite 210  
Carlsbad, CA 92008  
[www.synergieyes.com](http://www.synergieyes.com)  
Tel.: (760) 476- 9410  
FAX: (760) 476- 9340

# Table of Content

- INTRODUCTION..... 4
  - Product name List..... 4
- WEARING RESTRICTIONS AND INDICATIONS..... 5
- CONTRAINDICATIONS (Reasons Not To Use)..... 6
- WARNINGS ..... 6
- PRECAUTIONS..... 7
- ADVERSE REACTIONS: ..... 9
- PROCEDURES FOR HANDLING LENSES ..... 10
  - 1. Preparing the Lens for Wearing ..... 10
  - 2. Handling the Lenses ..... 11
  - 3. Placing the Lens on the Eye ..... 11
  - 4. Centering the Lens ..... 12
  - 5. Removing the Lens..... 12
- CARING FOR YOUR LENSES ..... 13
  - 1. Basic Instructions..... 13
  - 2. Care for a Sticking (Non-Moving) Lens ..... 15
  - 3. Chemical (Not Heat) Disinfection ..... 15
  - 4. Lens Deposits and Use of Enzymatic Cleaning Procedure ..... 16
  - 5. Lens Case Cleaning and Maintenance..... 16
  - 6. Emergencies ..... 16
- INSTRUCTIONS FOR THE MONOVISION WEARER..... 17
- INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (multifocal or monovision) ..... 17
- INSTRUCTIONS FOR THE PATIENT WITH KERATOCONUS, IRREGULAR CORNEA OR POST-SURGICAL CORNEA ..... 18
- WEARING AND APPOINTMENT SCHEDULES ..... 19

### *Commonly Used Terms*

**Cornea** The clear “window” of the eye, permitting light to enter, located in front of the iris and pupil

**Iris** – The colored part of the eye which controls the size of the pupil

**Pupil** – The black round opening surrounded by the iris

**Astigmatism** A common vision condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape causing the visual image to be out of focus (blurred)

**Presbyopia** The gradual loss of the eye’s ability to change focus from distance to near resulting in a need for additional correction for near tasks such as reading. The effects of presbyopia are generally first noticed after age 40

**Disinfect** A process which kills harmful microorganisms (germs) which can cause serious eye infections

**Lens Deposits** Particles such as cosmetics, lotions, and protein from the tear film, environmental pollutants, etc., which collect on the lens surface

## INTRODUCTION

This booklet explains how to safely use your Menicon Z™ (tisilfocon A) contact lenses. Read it and keep it in a safe place for future reference.

The Menicon Z™ (tisilfocon A) spherical, aspheric, toric and non-prism ballast multifocal lenses are intended for daily wear or extended wear. Toric lenses and prism ballast multifocal lenses are for daily wear use only. Lenses for the management of irregular corneas are available for daily wear only. The lens is available in a clear and a light blue tint with an ultraviolet absorber added (Benzotriazol).

## PRODUCT NAME LIST

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

<b>Product Name</b>	<b>Abbreviation</b>
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

<b>Product Name</b>	<b>Abbreviation</b>
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

## **WEARING RESTRICTIONS AND INDICATIONS**

The Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens is available as a spherical, aspheric, 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.

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

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.

The Menicon Z™ (tisilfocon A) Contact Lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care professional.

IF YOU ARE ON A DAILY WEAR SCHEDULE, DO NOT WEAR YOUR MENICON Z™ (TISILFOCON A) CONTACT LENSES WHILE SLEEPING. See **WARNINGS** for information about the relationship between wearing schedule and corneal complications.

**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.

## **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)
- Corneal hypoesthesia (reduced corneal sensitivity)
- 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 you follow your 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 should not be worn 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.<sup>1 2</sup>
- If you experience **eye** discomfort, excessive tearing, vision changes, or redness of the eye, you should **immediately remove lenses** and promptly contact your 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. You should continue to use your 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.

## PRECAUTIONS

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

### *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 your eye care professional's office, you should be able to promptly remove lenses or should have someone else available who can remove the lenses for you.
- 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.

---

<sup>1</sup> CLAO Journal, January 1996; Volume 22, Number 1, pp. 30-37

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

- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your 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 your 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, you should immediately consult your 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 Your Eye care Professional:*

- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

- Ask your eye care professional 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 your eye care professional before using any medicine in your 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. Always inform your eye care professional if you experience any problems with your lenses while taking such medications.

*Who Should Know That You Are Wearing Contact Lenses:*

- You should inform your doctor (health care professional) about 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 that the patient not wear contact lenses.

**ADVERSE REACTIONS:**

*The following problems may occur:*

- 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 you notice any of the above, you should:*

- 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 your 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, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, you should **immediately remove the lenses and consult your 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, you **should immediately remove the**

**lenses and contact your 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. You may avoid serious eye damage by contacting your 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.

## **PROCEDURES FOR HANDLING LENSES**

### **1. PREPARING THE LENS FOR WEARING**

It is essential that you learn and use good hygienic methods in the care and handling of your new 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 your lenses.

*The procedures are:*

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses. Proper hand washing can help to prevent eye infections.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to 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.

## **2. HANDLING THE LENSES**

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or cracks.

## **3. PLACING THE LENS ON THE EYE**

Always begin inserting your contact lenses with the same lens to avoid switching your lenses by mistake. Although your eye care professional will outline a method that is most suitable for you, here's a standard procedure for inserting and removing your lenses that you can always refer to \*:

\* If you are wearing large diameter, scleral lenses that cover your entire cornea, please see the special instructions below for inserting these lenses.

- a. Place the lens on the tip of the index finger with your dominant hand, concave side up.
- b. Hold your eyelids wide apart with the thumb and index finger of the other hand.
- c. Keep your eye wide open and slowly bring your lens up to the eye looking straight ahead. Gently place the lens on the cornea. Do not press the lens against your eye.
- d. Release the eyelids slowly and blink gently.
- e. Check your vision out of that eye to ensure the lens is in place before moving around to avoid accidental loss of a misplaced lens.
- f. Repeat this procedure for the other lens.

**NOTE:** IF IT IS EASIER, YOU CAN SWITCH HANDS. There are other methods of lens placement. If the above method is difficult for you, your eye care professional will provide you with an alternate method.

*Special Instructions for Placing the Scleral Lens on the eye:*

- a. Place the lens between the index and middle finger with the concave surface (side that goes onto your eye) facing upward.

- b. Completely fill the lens with the solution recommended by your eye care professional. This is very important to reduce the risk of unwanted air bubbles under the lens.
- c. With your head facing downward toward a table top, place the filled lens onto your eyes.
- d. Repeat this procedure for the other lens.

**NOTE: IF IT IS EASIER, YOU CAN SWITCH HANDS.** There are other methods of lens placement. If the above method is difficult for you, your eye care professional will provide you with an alternate method.

**Note:** If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "**Centering the Lens,**" next in this booklet).
- If the lens is centered, remove the lens (see "**Removing the Lens**" section) and check for the following:
  - a. Cosmetics or oils on the lens. Clean, rinse, disinfect and place on the eye again.
  - b. The lens is on the wrong eye.
  - c. The lens may be cracked, broken or damaged. If so, do not place the lens back on your eye.

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care professional.

#### **4. CENTERING THE LENS**

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens, follow the procedures below.

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

#### **5. REMOVING THE LENS**

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. Make sure with a mirror that the lens is in place.
- c. To remove the right lens, open your eyes as wide as possible and place the index finger of your right hand at the outer corner of your eyelid and look down into the palm of your left hand or into the center of a soft cloth placed on a flat surface.

- d. Keeping your eye open wide and your lens centered between your lids, pull eyelid gently toward the top of the ear.
- e. Blink once quickly.
- f. Your lens should fall out onto your hand or onto the cloth. Do not pry your lens loose or use a fingernail to remove it. If the lens does not come out, open wide and try again.
- g. Remove the other lens by following the same procedure.
- h. Follow the required lens care procedures described under the heading, **CARING FOR YOUR LENSES** (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING).

**Note:** if you are wearing scleral lenses, you may want to use the following method with a contact lens suction cup:

**Note:** If this method of removing your lens is difficult for you, your eye care professional will provide you with an alternate method.

## **CARING FOR YOUR LENSES**

(CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING)

### **1. BASIC INSTRUCTIONS**

For continued safe and comfortable wearing of your lenses, it is important that you **first clean and rinse, then disinfect** your lenses after each removal, using the care regimen recommended by your eye care professional. **Cleaning and rinsing** are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean your lenses is 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 the regimen may result in development of serious ocular complications as discussed in the **WARNINGS** section above. If you require vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure you put the lenses on and remove them while you are in your eye care professional's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eye care professional should instruct you about appropriate and adequate procedures and

products for your use, and provide you with a copy of the Patient Instructions for the Menicon Z™ (tisilfocon A) Contact Lens.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.
- Use the recommended system of lens care, chemical (not heat), and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eye care professional. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

The lens care products listed below are recommended for use with your Menicon Z™ (tisilfocon A) Contact Lenses. See Package Insert for other products that may be used with this lens. Your eye care professional may recommend alternate solutions that are appropriate for you to use with your Menicon Z™ (tisilfocon A) Contact Lenses. Each lens care product contains specific directions for use and important safety information, which you should read and carefully follow. Avoid the use of abrasive surfactant cleaners such as Boston® , Boston Advance® , Opti-Free® and Opti-Soak®.

### *Lens Care Table*

<b>Solution Purpose</b>	<b>Lens Care System</b>
	<b>Chemical (not heat) disinfection</b>
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 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 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), **rinse** the lens thoroughly with recommended rinsing solution to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. 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 your eye care professional and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.
- 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, you should consult the package insert or the eye care professional for information on storage of your lenses.
- Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eye care professional for a recommendation on how to store your lenses.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) 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 fresh storage solution. Replace lens case at regular intervals.
- Your eye care professional may recommend a lubricating/rewetting solution for your use. **Lubricating/Rewetting** solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.
- Menicon Z™ (tisilfocon A) Contact Lenses cannot be heat (thermally) disinfected.

## 2. CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), you should 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 non-movement of the lens continues after 10 minutes, you should immediately consult your eye care professional.

## 3. 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 solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution or 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 prior to placement on the eye should reduce the potential for irritation.

#### **4. LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE**

Enzyme cleaning may be recommended by your 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 your lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation. For extended wear patients in particular, enzymatic cleaning is recommended each time the lenses are removed for an overnight break. Daily wear patients have also been shown to benefit from periodic enzymatic cleaning. 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, you should carefully follow the instructions in the enzymatic cleaning labeling.

#### **5. LENS CASE CLEANING AND MAINTENANCE**

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. Never add fresh solution to old solution since this can increase the risk of lens and lens case contamination and eye infection. You should replace lens cases at regular intervals as recommended by the lens case manufacturer or your eye care professional.

#### **6. EMERGENCIES**

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

**FLUSH EYES IMMEDIATELY WITH TAP WATER OR FRESH STERILE SALINE SOLUTION AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

## **INSTRUCTIONS FOR THE MONOVISION WEARER**

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty 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 as adaptation takes place. 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 these 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 lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care professional having additional contact or spectacle lenses 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 or spectacle lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eye care professional.
- It is important that you follow your eye care professional's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with a monovision correction is most appropriately left to the eye care professional in conjunction with you, after carefully considering and discussing your needs.

## **INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (MULTIFOCAL OR MONOVISION)**

Two common methods of using contact lenses for presbyopic vision correction include multifocal or bifocal lenses, and monovision. Like bifocal, trifocal, or progressive addition spectacles, 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 the other eye.

As with any type of lens correction, there are advantages and compromises with multifocal or monovision correction. The benefit of clear near vision in straight-ahead and upward gaze that is available may be accompanied by reduced vision at certain distances or under certain lighting conditions. Some individuals, particularly those wearing monovision lenses may experience reduced depth perception. Some patients experience difficulty adapting to this. Symptoms such as mild blurring, dizziness, headaches and a feeling of slight imbalance, may last briefly or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation.

During the adaptation period it is recommended that you wear these contact lenses only in familiar situations which are not visually demanding. For example, you should avoid driving an automobile until you are comfortable that your eyes have adjusted. It is recommended that you drive with multifocal or monovision correction only if you can pass the driver's license requirements with your lenses.

- Some patients will never be fully comfortable functioning in low light, such as driving at night. If this happens, you may want to discuss with your eye care professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance vision is required.
- If you perform prolonged close work requiring very sharp near vision, you may need to wear spectacles over your lenses or have additional lenses prescribed specifically for this task. You should discuss your specific visual needs with your eye care professional.
- It is important that you follow your eye care professional's advice regarding adaptation to presbyopic vision correction. During the adaptation period you should make careful note of any specific situation where you feel unable to function effectively and safely, and discuss these concerns with your eye care professional.
- The decision to be fit with multifocal lenses or a monovision correction should be made in conjunction with your eye care professional only after carefully considering and discussing your needs.

## **INSTRUCTIONS FOR THE PATIENT WITH KERATOCONUS, IRREGULAR CORNEA OR POST-SURGICAL CORNEA**

- Your lenses should be worn for daily wear only (no overnight wear). You should NOT wear your lenses while sleeping. No clinical studies have been done to establish the safety of sleeping in these lenses for patients with keratoconus, irregular corneas or post-surgical corneas. Clinical studies have shown that the risk of serious adverse reactions is increased when daily wear lenses are worn overnight.
- Your eye care professional should determine the appropriate wearing schedule for your individual needs. It is very important to carefully follow these

recommendations and your eye care professional’s specific instructions regarding lens care, insertion and removal.

**WEARING AND APPOINTMENT SCHEDULES**

YOUR WEARING SCHEDULE SHOULD BE DETERMINED BY YOUR EYE CARE PROFESSIONAL.

Since most patients initially tend to over wear contact lenses, it is important to adhere to the initial maximum wearing schedule established by your eye care professional. In no event should your initial maximum wearing schedule exceed the schedule set forth below. Regular checkups, as determined by your eye care professional are also extremely important.

Do not skip visits with your eye care professional just because your lenses feel comfortable. Routine follow-up visits help prevent problems. Only a thorough examination by your eye care professional can determine how your eyes are responding to 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 your eye care professional is necessary. Your eye care professional should determine the appropriate wearing time and provide you with specific instructions regarding lens care, insertion and removal.

**WARNING:** If you are fit with Menicon Z™ (tisilfocon A) contact lenses for the management of keratoconus or other types of irregular cornea you should NOT wear your lenses overnight or while sleeping in them. If you have keratoconus or another type of irregular corneal condition, wearing lenses while asleep can cause serious adverse reactions or loss of vision. It is essential that your wearing schedule be individually determined by your eye care professional.

The maximum suggested wearing time for the Menicon Z™ (tisilfocon A) Contact Lens 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.

*PRESCRIBED WEARING SCHEDULE*

Day	Wearing Time (Hours)
1	_____
2	_____
3	_____
4	_____
5	_____
6 and after	_____

*APPOINTMENT SCHEDULE*

Your appointments are on:

**Minimum number of  
hours lenses to be worn**

Month	Year	Time	Day at time of appointment
-------	------	------	----------------------------

*PATIENT/EYE CARE PROFESSIONAL INFORMATION:*

Eye care Professional Information

Eye care Professional Name: \_\_\_\_\_

Practice Name: \_\_\_\_\_

Eye care Professional Address: \_\_\_\_\_

Eye care Professional Phone Number: \_\_\_\_\_

Recommended Lens Care Regimen:

Cleaning Solution: \_\_\_\_\_

Rinsing Solution: \_\_\_\_\_

Disinfecting Solution: \_\_\_\_\_

Lubricating Solution: \_\_\_\_\_

Insertion of sclera lenses: \_\_\_\_\_

**IMPORTANT:** In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PROFESSIONAL IMMEDIATELY.

Print Date 2017-02-28