

PROFESSIONAL FITTING AND
INFORMATION GUIDE

Menicon Z™ (tisilfocon A)

Rigid Gas Permeable Contact Lenses

CAUTION: Federal Law Prohibits Dispensing Without a Prescription

Menicon Z

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INTRODUCTION:

The Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens is a thermoset copolymer derived from fluoro-methacrylate and siloxanylstyrene, bound by crosslinking agents. The lens is available in a light blue tint. The lens is tinted with color additive D & C Green No. 6. Also, UV absorber is added (Benzotriazol).

For a complete list of available lens parameters, please refer below.

DESCRIPTION:

The Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lens is available as a daily wear spherical, aspheric, prism ballast toric or multifocal design and as an extended wear spherical non-prism ballast toric or aspheric design.

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 light blue tint. The lens is tinted with color additive D & C Green No. 6. Also, UV absorber (Benzotriazol) is added as an additive during the manufacturing process.

NOTE: The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time.

LENS PARAMETERS AVAILABLE

(Note: not all parameter combinations are available in all designs)

Spherical and aspherical lens:

Diameter	7.0 to 12.0 mm
Center Thickness	0.08 to 0.50 mm
Base Curve	6.50 to 9.00 mm (in 0.05 mm steps)
Powers	-25.00 to +20.00 D (in 0.25 D steps) -20.00 to +12.00 D (in 0.25 D steps) (extended wear)

Toric lens:

Diameter	7.0 to 11.0 mm
Center Thickness	0.08 to 0.50 mm
Base Curve	7.30 to 8.50 mm
Sphere Powers	-10.00 to +10.00 D (in 0.25 D steps)
Cylinder Powers	-0.50 to -5.00 D (in 0.25 D steps)
Prism Ballast	0.75 to 2.00 D (in 0.25 D steps)
Truncation Height	0.0 to 1.0 mm (in 0.1 mm steps)

Multifocal Lens (Concentric, De-centered, Crescent):

Diameter	8.0 to 11.0 mm
Center Thickness	0.08 to 0.65 mm
Base Curve	7.30 to 8.50 mm
Sphere Power	+6.00 to -10.00 D
Add Power	+0.75 to +3.00 D

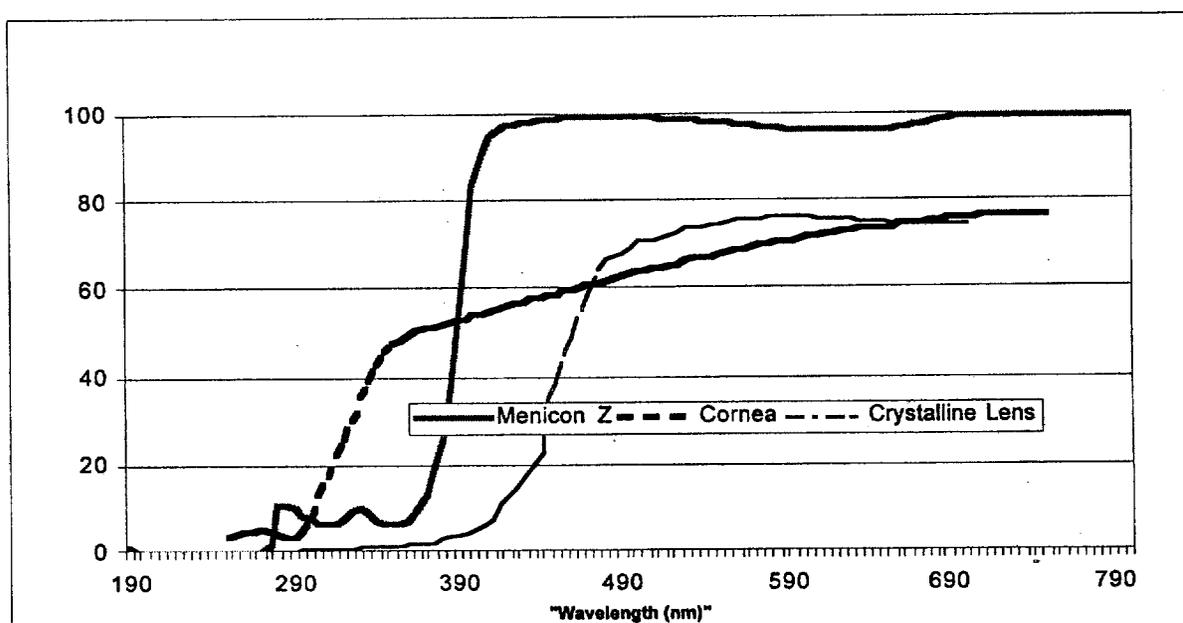
The physical/optical properties of the lens are:

Specific Gravity: 1.20
 Refractive Index: n_D^{25} 1.436 \pm 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 0.08 mm)
 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)



MENICON Z RGP - Spectral transmittance curve for Menicon Z (tisilfocon A) Contact Lens - D & C Green No. 6 and UV absorbing agent (sample thickness Menicon Z lens polymer plate = 0.08 mm, 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.

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 rigid gas permeable contact lens is a lathe cut firm contact lens with spherical or aspherical 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 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 Multifocal Contact Lens provides the necessary optical powers to correct different refractive errors for distance and near requirements.

INDICATIONS (USES):

Menicon Z (tisilfocon A) spherical, aspheric, prism ballast, toric and 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.

Menicon Z (tisilfocon A) spherical or aspheric lenses and non-prism ballast toric lenses are indicated for extended wear (from 1 to 7 days between removals for cleaning and disinfection of the lenses, as recommended by the eyecare practitioner) for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in non-aphakic persons with non-diseased eyes.

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

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 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 patients follow their eyecare 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 are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens users.
- 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 eyecare 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.

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 practitioner for more information.

PRECAUTIONS:

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

Special Precautions for Eyecare Professionals:

- Lenses are shipped in a vial immersed in Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution. If the vial has missing solution or is dry, return the product to Menicon according to Menicon return policies.
- If continual wet storage of wet shipped contact lenses is preferred, the Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution should be changed every 30 days from the hydration date.
- If the patient is sensitive to edetate disodium or chlorhexidine gluconate, the lens should be removed from the vial upon receipt, rinsed with fresh saline solution, cleaned with a cleaner and place in another prescribed disinfecting solution prior to dispensing. Follow the manufacturer's instructions on the disinfecting solution label.

- 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 design and parameters, the eyecare professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare professional.

- Aphakic and other post-surgical persons should not be fitted with Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eyecare 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.
- The eyecare professional 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 contact lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)
- 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.

Eyecare professionals should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
 - Always use fresh unexpired lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - 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.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.

- Always keep the lenses completely immersed in 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.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eyecare professional.
- 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-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the Menicon Contact Lens and any instructions prescribed by the eyecare professional.
- Never wear lenses beyond the period recommended by the eyecare professional.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare professional about wearing lenses during water activities and other sports.
- Inform the doctor (health care professional) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use.
- Do not touch the lens with fingernails.
- Always contact the eyecare professional before using any medicine in the eyes.
- 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.
- 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.

ADVERSE REACTIONS:

The patient should be informed that 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
- 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 eyecare 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 eyecare professional.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

SELECTION OF PATIENTS :

Menicon Z (tisilfocon A) spherical or aspheric lenses are indicated for daily wear or extended wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

Menicon Z (tisilfocon A) toric and 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.

Persons who require only vision correction and who would not or could not adhere to a recommended care regimen for Menicon Z (tisilfocon A) Contact Lens or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensuring patient compliance.

It is necessary to make an assessment of general health, patient hygiene, motivation and the willingness to comply with practitioner instructions.

PREPARING AN RGP LENS FOR FITTING :

Menicon Z (tisilfocon A) Contact Lenses should be thoroughly cleaned with the recommended cleaning solution and hydrated in the desired soaking/conditioning solution for at least 4 hours prior to placement on the eye to insure maximum surface wettability.

PRE-FITTING EXAMINATION :

A pre-fitting patient history and examination are necessary to :

- determine whether a patient is a suitable candidate for daily wear contact lenses (consider patient hygiene and mental and physical state),

- make ocular measurements for initial contact lens parameter selection,

- collect and record baseline clinical information to which post-fitting examination results can be compared.

Initial evaluation of the trial lens should be preceded by a complete eye examination including visual acuity with and without correction at both distance and near, keratometry and Slit Lamp Examination of the cornea, bulbar conjunctiva, and limbus, anterior chamber and tarsal abnormalities.

The following evaluations apply to all lens designs:

1. Characteristics of a Well-Fit Lens

A good fit positions appropriately following the blink with minimal lag and the optical portion of the lens does not deviate from the pupil when the lens is drawn upwards. Ideally, the lens will ride up with the blink and then quickly return to a position of rest.

2. Characteristics of a Steep Lens

A steep lens usually shows restricted movement. The fluorescein pattern will show central pooling, excessive intermediate bearing with inadequate edge lift.

3. Characteristics of a Flat Lens

A flat lens will often position high under the upper lid or drop rapidly when released from the lid. This lens may be comfortable for the patient, but often provides an unfavorable visual response. The fluorescein pattern will show central bearing or touch when the lens is centered on the eye. Horizontal decentration or movement may also indicate a flat lens.

4. Fluorescein Evaluation

The fluorescein pattern should indicate good tear exchange with an alignment lens to cornea relationship. The presence of the ultraviolet (UV) light absorber in the Menicon Z contact lens material requires modification of the Burton lamp to visualize fluorescein patterns adequately. Burton lamp conversion kits are available upon request by calling Menicon at 1-800-636-4266.

FITTING PROCEDURE :

General Prescribing and Fitting Guidelines

Menicon provides the contact lens fitting professional with a choice of designs to accommodate almost any physical and optical requirements. Spherical lenses and aspheric designs are sufficient for the majority of single vision and monovision prescribing needs, and toric and multifocal lenses are available for patients with more specialized fitting and/or optical needs. The general requirements and recommendations for fitting each type of lens are detailed below.

1. SPHERICAL AND ASPHERIC DESIGNS

a. Initial Design Selection

The table below lists the various spherical and aspheric designs available from Menicon, and recommendations for use.

Design	Description	Recommended uses
Thin, Thin X	<ul style="list-style-type: none"> Thin design (0.15mm for -3.00, 0.10 mm min.) Diameters 8.0 to 11.0 Designed for alignment fit with lid interaction Lenticulation designed to provide uniform edge profiles Moderate to high edge lift 	<ul style="list-style-type: none"> First time rigid contact lens wearers Previous wearers of thin lens designs Patients in whom inferior decentration or excess post-blink movement has been observed Persistent peripheral corneal desiccation (3&9 staining) cases Low to moderate with-the-rule astigmatism Available for inventory fitting
Aspheric	<ul style="list-style-type: none"> Back surface low eccentricity aspheric design with junctionless periphery Diameter varies with base curve (9.0 to 9.8 mm) Thin design (0.13 for -3.00, 0.11 mm min.) Base curves available in 0.10 mm increments Designed for alignment fit, with diameters to provide under lid positioning Low to moderate edge lift 	<ul style="list-style-type: none"> First time contact lens wearers Soft toric candidates Moderate with-the-rule astigmatism Very helpful in cases where centration not ideal with spherical design Easy to fit, design, order Available for inventory fitting
Alpha 1	<ul style="list-style-type: none"> The original Menicon design Diameters 8.8, 9.2 and 9.6 mm Designed for interpalpebral or under lid alignment philosophy Lenticulars standard to provide uniform edge profile across powers Low to moderate edge lift Standard thickness (0.18 for -3.00, 0.12 mm min.) 	<ul style="list-style-type: none"> Current satisfied Alpha 1 users or wearers of other standard thickness spherical designs Moderate to high with-the-rule astigmatism or irregular corneas Use when added mass or weight or thickness is desirable to minimize lid interaction

b. Initial Lens Diameter Selection

Lens centration and the interpalpebral distance are important factors in selecting a lens diameter. A diameter between 9.2 mm and 9.6 mm is recommended for lenses where a diameter choice is required. Ideally, the upper edge of the lens should be located at or near the superior lid and remain covered by the upper lid margin during the full cycle of each blink. It is important to verify that the optical zone of the lens covers the pupil adequately in dim light.

c. Initial Base Curve Selection

Menicon Thin Design

Corneal Astigmatism	9.2 mm Diameter	9.6 mm Diameter
Spherical to 0.75 D	on K_{flat}	0.25 D (0.05 mm) flatter than K_{flat}
1.00 D to 1.75 D	0.25 D (0.05 mm) steeper than K_{flat}	on K_{flat}
2.00 D to 2.50 D	0.50 D (0.10 mm) steeper than K_{flat}	0.25 D (0.05 mm) steeper than K_{flat}
over 2.50 D	toric lens recommended	toric lens recommended

Menicon Alpha 1 Design

Corneal Astigmatism	8.8 mm Diameter	9.2 mm Diameter	9.6 mm Diameter
0 to 0.75 D	on K	0.25 D FTK _{flat}	0.50 D FTK _{flat}
>1.00 to 1.75 D	0.25 D STK _{flat}	on K	0.25 D FTK _{flat}
>2.00 to 2.50 D	0.50 D STK _{flat}	0.25 D STK _{flat}	on K_{flat}
> 2.50 D	Recommend toric	Recommend toric	Recommend toric

Menicon Aspheric Design

Corneal Astigmatism	Base Curve Selection
0 to 0.75 D	Fit on K_{flat} (round to next flatter BC)
1.00 to 1.75 D	Fit on K_{flat} (round to next steeper BC)
2.00 to 2.50 D	Fit 0.10 mm steeper than K_{flat} (round to next steeper BC)
greater than 2.50 D	Consider bitoric design

d. Initial Lens Power Selection

- 1) Convert Rx to minus cylinder if necessary.
- 2) Correct for vertex distance if either meridian is greater than -4.00 using vertex distance chart.
- 3) Power will be equal to spherical component of the spectacle correction (corrected for vertex distance expressed in minus cylinder format) for an "On-K" fit.
- 4) SAMFAP (Steeper Add Minus Flatter Add Plus) correction must be made if the lens is steeper or flatter than K (or than the trial lens used). Change the power by the dioptric equivalent of the change in base curve.

e. Characteristics of a Well-Fit Spherical/Aspheric Lens

- The lens should center over the pupillary zone on the cornea.
- The lens should move freely with the blink.
- The fluorescein pattern should show good tear exchange.

2. MENICON TORIC DESIGNS**General Prescribing and Fitting Guidelines**

The decision to move from a spherical to a toric lens design is based upon two factors, physical fit and optical requirements. Lenses can be designed with toric shapes and toric optics, toric shapes and spherical optics, or spherical back surfaces with toric optics. To help determine whether a toric lens is needed, the fitting professional should answer the following two questions.

- 1) Is there more than 2.50 D with-the-rule (WTR) or 1.50 D against-the-rule (ATR) corneal astigmatism (as measured by keratometry or topography)?

If yes, a toric back surface shape is recommended for an optimal lens-to-cornea relationship.

Calculation method:

- Subtract K reading closest to vertical or 90 degrees (K_v) from K reading closest horizontal or 180 degrees (K_h) using the dioptric values to get the corneal astigmatism value and orientation

→ negative values indicate WTR astigmatism

→ positive values indicate ATR astigmatism

EXAMPLE: K's: 43.00@180/46.00@90

$$K_h - K_v = 43.00 - 46.00 = -3.00 \text{ D (WTR)}$$

- 2) Is there a difference of more than 0.75 D between the amount of corneal astigmatism (as measured by keratometry or topography) and the amount of refractive cylinder in the spectacle refraction (corrected for vertex distance to the corneal plane and expressed in minus cylinder format)?

If yes, toric optics may be required to provide optimal visual acuity.

Calculation method:

- Transpose spectacle Rx to minus cylinder format if necessary.
- Correct for vertex distance if either meridian exceeds ± 4.00 diopters.
- Making sure signs are maintained, subtract the corneal cylinder (Cyl_K) from refractive cylinder (Cyl_{Rx}).

EXAMPLE: K's: 43.00@180/46.00@90; Rx_{Spec} : -6.75 + 3.75 x 90

Correct for vertex distance -6.25 + 3.25 x 90

Transpose to minus cyl: -3.00 - 3.25 x 180

$Cyl_{Rx} - Cyl_K$: -3.25 - (-3.00) = -0.25 (spherical optics will be adequate)

The table below details the indications for the single vision designs offered by Menicon USA:

Design	Corneal cylinder	Refractive cylinder (at cornea)
Spherical or Aspheric	Low (under 2.50 WTR or 1.50 ATR)	$Cyl_{Rx} \sim Cyl_K$
Back Toric	Moderate to high (over 2.50 WTR or 1.50 ATR)	$Cyl_{Rx} \sim 1.5X Cyl_K$
Front Toric	Low (under 2.50 WTR or 1.50 ATR)	$Cyl_{Rx} - Cyl_K > 0.75D$
Bitoric (SPE) Spherical optics	Moderate to high (over 2.50 WTR or 1.50 ATR)	$Cyl_{Rx} \sim Cyl_K$
Bitoric (CPE) Toric optics	Moderate to high (over 2.50 WTR or 1.50 ATR)	$Cyl_{Rx} - Cyl_K > 0.75D$

a. Diameter selection

Menicon recommends beginning with a moderate diameter (9.0 to 9.4 mm). The horizontal diameter should provide coverage of approximately 80% of the horizontal visible iris diameter.

b. Base curve selection

The base curve for a front toric design should be selected according to the rules for a spherical lens.

For toric base curves (back torics and bitorics), the flat curve should be selected according to the rules for a spherical lens. The second curve should be steeper by an amount approximately 1 diopter less than the total corneal astigmatism for with-the-rule corneas to allow for movement and tear exchange. For against-the-rule corneas, up to 100% of the back surface astigmatism can be corrected to provide horizontal stability.

EXAMPLE: K's: 43.00@180/46.00@90

$K_H - K_V = 43.00 - 46.00 = -3.00$ (WTR) or 3 D total corneal astigmatism

Flat BC = on flat K = 43.00 D (7.85mm)

Steep BC = 3 - 1 or 2 diopters steeper = 45.00 D (7.50 mm)

c. Power Selection

Front toric

Perform a sphero-cylindrical over-refraction of the best fitting spherical lens, and add the over-refraction to the power of the spherical lenses. Generally 1.00 to 1.50 prism base down is added to stabilize the lens. The prism base can be moved in (base toward the patient's nose) or out (base toward patient's ear) to compensate for lens rotation if required.

EXAMPLE:

Spherical trial lens:	BC 7.80	DIA 9.2	POWER -3.00
Best spherical over-refraction		-1.00 DS	VA: 20/30
Sphero-cyl over-refraction:		-0.50 - 1.00 x 90	VA 20/15
Lens order:	7.80 9.2	-3.50 -1.00 x 90	1 p.d. base down

Back toric

The use of a back toric only lens is rare, usually occurring in cases of significant against-the-rule corneal astigmatism. In these cases, the power determination is usually performed empirically. When the refractive astigmatism to corneal astigmatism ratio is between 1.3 and 1.5, a toric base lens is indicated.

EXAMPLE: K's: 45.00/43.00@90 (pl - 2.00 x 90)
 RX: +2.00 - 3.00 x 90
 Refractive/Corneal cyl ratio = $3/2 = 1.5$ (back toric indicated)

Select base curves equal to corneal cylinder for ATR cornea
 → 43.00/45.00 for 9.2 mm lens

Calculate the spherical power as for a spherical lens; the additional toric power needed will be created by the back surface. NOTE: This lens will have a cylindrical power when read in a lensometer.

SPE Bitoric:

An SPE bitoric corrects only corneal astigmatism, just as a spherical lens does. The powers on an SPE are just as simple to calculate. The first power is calculated exactly as for a spherical lens, using the BC-cornea relationship and the SAMFAP rule, as outlined in the spherical fitting section. The second power is determined by the amount of toricity of the back surface of the lens. The second power will be more minus than the first by the dioptic value of the back surface cylinder.

EXAMPLE: K's: 43.00@180/46.00@90; Rx_{corneal plane}: - 1.00 - 2.75 x 180
 BC selection (2 D toricity, on K): 7.85/7.50mm (43.00/45.00D)
 Power: -1.00/-3.00 (on K/2 D more minus)

CPE Bitoric:

A CPE bitoric corrects all refractive astigmatism, similar to a front toric. Its effectiveness will be affected by lens orientation and stability, as with front toric lenses. The powers on a CPE lens are best calculated as two separate lenses, one for the flat meridian and one for the steep meridian. Each meridian is calculated exactly as for a spherical lens, using the BC-cornea relationship and the SAMFAP rule, as outlined in the spherical fitting section.

EXAMPLE: K's: 43.00@180/46.00@90; Rx_{corneal plane}: - 1.00 - 3.75 x 180
 Flat meridian: 43.00/-1.00; on K fit, 9.2 mm diameter → 7.85 mm (43.00D) / -1.00
 Steep meridian: 46.00/-4.75; fit 1 D flat, 9.2 mm diameter → 7.50 mm (45.00D) / -3.75

Final lens order: 7.85/7.50 (43.00D/45.00D); 9.2 mm diameter; -1.00/-3.75

3. MULTIFOCAL LENSES

Menicon Decentered Target Design Lens Fitting Procedure

The Menicon Decentered Target design is a one-piece, back surface add bifocal which works primarily on the alternating or translating vision principle. It features a round distance zone decentered superiorly which allows a combination of simultaneous and translating vision options for optimal viewing at all distances. The back surface add eliminates image jump and associated blur or doubling at the distance-near junction.

The Decentered Target design is excellent for patients who would do well in a spectacle lens with a progressive style of near add, who have the following characteristics:

Physical Features

Aperture size normal to large
 Lower lid at or above lower limbus in primary gaze
 Upper lid in upper 1/3 or cornea or higher
 Pupil size average to large
 Spherical or low to moderate with-the-rule corneas

Viewing Demands

Heavy near and intermediate requirements
 Near and/or intermediate demands in all gazes
 Add requirements minimal to high

a. Diameter selection

Menicon recommends beginning with a moderate diameter with truncation for the initial lens (9.4/9.0 mm). Lenses which are too large in the vertical diameter may interact excessively with the upper lid causing a lens which is held too high or too long after the blink, or which gets forced down behind the lower lid on down gaze.

The horizontal diameter should provide coverage of approximately 80% of the horizontal visible iris diameter. Vertically, the lower edge of the lens should rest on the lower lid or at the lower limbus, with the upper edge of the lens resting at or just under the upper lid margin. Generally, problems with lens translation should be addressed by altering the vertical (truncated) dimension of the lens. If the lower lid is too low to allow positioning of the optical zone over the pupil without excessive upper lid interaction, a centered target design should be used.

b. Base curve selection

The base curve should be selected to be approximately equal to or 0.50 D steeper than the flattest keratometry reading. Steeper curves will limit the ability of the lens to translate up on down gaze, while flatter curves may result in lens instability. The Centered Target or Crescent Seg toric designs are indicated when corneal astigmatism exceeds 2.50D.

c. Power selection

The distance power of the diagnostic lens should be as close to the patient's actual power as possible. The initial power should be calculated using the procedure outlined for spherical lenses. Distance power should be adjusted according to the over-refraction of the trial lenses using a trial frame and/or loose lenses whenever possible. The near add power should be approximately equal to the add power required in spectacle lenses. Add power should be assessed using the range of useable vision for the required text size rather than strictly by visual acuity.

d. Seg height and distance zone size selection

Menicon recommends an initial seg height of 4.0 mm with a 4.5 mm distance zone. When viewed with fluorescein, the distance zone should be visible as a bright green round pool centered over the pupil in primary gaze. Seg height should be evaluated with the best distance over-refraction in place in trial lenses (do not use a phoropter for near testing). The patient should place normal reading material at their normal reading distance at a point just above eye level, and move it down in an arc to their normal reading position, keeping their chin up and moving only their eyes. Ask them to note when the print changes from blurry to clear. This transition zone should be located midway between their normal distance and near viewing zones. Small movements of the chin up and down can be used to reposition the transition zone temporarily for viewing objects in the intermediate area.

A change of 0.1 mm in seg height will result in a 1-2" change in the position of the transition zone. *Example: If the patient has to move the reading material down 3-4" more than is comfortable for reading, the seg height should be raised approximately 0.3 mm.*

The distance optic zone may be made up to approximately 5 mm depending on add power. If optimal distance viewing cannot be obtained with proper seg height adjustments and zone size manipulations, the Crescent Design should be used.

e. Characteristics of a well-fit Menicon Decentered Target Design Lens

- lens rests on the lower lid margin or at the inferior limbus with the upper edge near the upper lid margin
- lens moves up minimally with the blink and quickly returns to its resting position at the lower lid
- the lens should translate up freely on down gaze, with the truncation remaining on the lower lid during translation
- the distance-to-near transition zone should be intermediate between the patient's habitual reading position and primary gaze

Menicon Crescent Seg Design Lens Fitting Procedure

The Menicon crescent seg design is a one-piece, front surface add bifocal which works on the alternating or translating vision principle. It offers a large distance viewing zone as well as a large near area for maximum visual performance in all gazes.

The Crescent seg design is excellent for patients who would do well in a spectacle lens with a Flat top or "D" segment, who have the following characteristics:

<u>Physical Features</u>	<u>Viewing Demands</u>
Aperture size normal to large	Mainly distance & near viewing requirements
Lower lid at or above lower limbus in primary gaze	Few intermediate demands
Upper lid in upper 1/3 or cornea or higher	Add requirements moderate to high
Pupil size average to small	
Nearly any corneal and/or refractive cylinder can be corrected	

a. Diameter selection

Menicon recommends beginning with a moderate diameter with truncation for the initial lens (9.4/9.0 mm). Lenses which are too large in the vertical diameter may interact excessively with the upper lid causing a lens which is held too high or too long after the blink, or which gets forced down behind the lower lid on down gaze.

The horizontal diameter should provide coverage of approximately 80% of the horizontal visible iris diameter. Vertically, the lower edge of the lens should rest on the lower lid or at the lower limbus, with the upper edge of the lens resting at or just under the upper lid margin. Generally, problems with lens translation should be addressed by altering the vertical (truncated) dimension of the lens. If the lower lid is too low to allow positioning of the optical zone over the pupil without excessive upper lid interaction, a centered target design should be used.

b. Base curve selection

The base curve should be selected to be approximately equal to or 0.50 D flatter than the flattest keratometry reading. Steeper curves will limit the ability of the lens to translate up on down gaze. Bitoric designs are indicated when corneal astigmatism exceeds 2.50D.

c. Power selection

The distance power of the diagnostic lens should be as close to the patient's actual power as possible. The initial power should be calculated using the procedure outlined for spherical lenses. Distance power should be adjusted according to the over-refraction of the trial lenses using a trial frame and/or loose lenses whenever possible. The near add power should be approximately equal to the add power required in spectacle lenses. Add power should be assessed using the range of useable vision for the required text size rather than strictly by visual acuity.

d. Seg height selection

Menicon recommends an initial seg height of 4.0 mm. Seg height should be evaluated with the best distance over-refraction in place in trial lenses (do not use a phoropter for near testing). The patient should place normal reading material at their normal reading distance at a point just above eye level, and move it down in an arc to their normal reading position, keeping their chin up and moving only their eyes. Ask them to note when the print changes from blurry to clear. This transition zone should be located midway between their normal distance and near viewing zones. Small movements of the chin up and down can be used to reposition the transition zone temporarily for viewing objects in the intermediate area.

A change of 0.1 mm in seg height will result in a 1-2" change in the position of the transition zone. *Example: If the patient has to move the reading material down 3-4" more than is comfortable for reading, the seg height should be raised approximately 0.3 mm.*

If the patient does not adapt to the presence of the transition zone within 1 to 2 weeks of wear, a no-jump design (Target or Decentered Target) should be used.

e. Characteristics of a well-fit Menicon Crescent Seg Design Lens

- lens rests on the lower lid margin or at the inferior limbus with the upper edge near the upper lid margin
- lens moves up minimally with the blink and quickly returns to its resting position at the lower lid
- the lens should translate up freely on down gaze, with the truncation remaining on the lower lid during translation
- the distance-to-near transition zone should be intermediate between the patient's habitual reading position and primary gaze

Menicon Centered Target Design Lens Fitting Procedure

The Menicon Centered Target design is a one-piece, back surface add bifocal which works primarily on the simultaneous vision principle and does not require lower lid interaction for optimal performance. It features a round centered distance zone with a surrounding near zone which allows many patients full intermediate viewing for computer and dashboard viewing. The back surface add eliminates image jump and associated blur or doubling at the distance-near junction.

The Centered Target design is excellent for patients who have the following characteristics:

Physical Features

Ideal for small apertures

Works well with very large apertures or where lower lid is below lower limbus

Pupil size average to large

Spherical or with-the-rule corneas best

Toric back and front surfaces available to accommodate most corrections

Viewing Demands

Heavy near and intermediate requirements

Near and/or intermediate demands in all gazes

Add requirements minimal to high

a. Diameter selection

Menicon recommends beginning a moderate diameter for the initial lens (9.0 to 9.4 mm). The horizontal diameter should provide coverage of approximately 75-80% of the horizontal visible iris diameter.

b. Base curve selection

The base curve should be selected to be approximately equal to or 0.50 D steeper than the flattest keratometry reading. Toric designs are indicated when corneal astigmatism exceeds 2.50D.

c. Power selection

The distance power of the diagnostic lens should be as close to the patient's actual power as possible. The initial power should be calculated using the procedure outlined for spherical lenses. Distance power should be adjusted according to the over-refraction of the trial lenses using a trial frame and/or loose lenses whenever possible. The near add power should be approximately equal to the add power required in spectacle lenses. Add power should be assessed using the range of useable vision for the required text size rather than strictly by visual acuity.

d. Distance zone size selection

Menicon recommends an initial distance zone size of 3.5 to 4.0 mm. When viewed with fluorescein, the distance zone should be visible as a bright green round pool centered over the pupil in primary gaze. Near vision performance should be evaluated with the best distance over-refraction in place in trial lenses (do not use a phoropter for near testing). The patient should place normal reading material at their normal reading and position, keeping their chin up and moving only their eyes to view near objects. Small movements of the chin up and down can be used to optimize near viewing.

It is sometimes helpful to place a larger distance zone over the dominant eye to optimize distance viewing, with a smaller zone on the other eye to optimize near viewing.

e. Characteristics of a well-fit Menicon Centered Target Design Lens

- lens is well centered throughout the blink cycle
- lens moves up minimally with the blink and quickly returns to a centered position
- the lens should translate up slightly on down gaze
- the round green circle of fluorescein should cover the pupil and be centered or displaced slightly high but still covering the pupil when viewed with a Burton lamp or slit lamp
- The transition zone, if noticed, should be intermediate between the patient's habitual reading position and primary gaze

FOLLOW - UP CARE FOR ALL LENSES :

- a. Follow-up examinations, as recommended by eyecare professional, are necessary to ensure continued successful contact lens wear. An unscheduled visit may be indicated whenever the wearer reports a change in vision, ocular discomfort, or redness of the eye.
- b. Prior to a follow-up examination, the contact lenses should be worn for at least four continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

- c. With lenses in place on the eyes, evaluate fitting performance to assure that characteristics of a well-fit lens continue to be satisfied for the appropriate lens design. Examine the lenses closely for surface deposition and/or damage.
- d. After the lens removal, instill sodium fluorescein into the eyes and conduct a thorough biomicroscopy examination.
 - 1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
 - 2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
 - 3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the characteristics of a well-fit lens are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

IN OFFICE CARE OF TRIAL LENSES :

Eyecare professionals should educate contact lens technicians concerning proper care of trial lenses.

Each Menicon Z (tisilfocon A) lens is shipped non-sterile in an individual plastic container. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens.

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

RECOMMENDED INITIAL WEARING SCHEDULE :

Although many professionals have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare professional regardless of how comfortable the lenses feel.

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

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

Daily Wear (During Waking Hours)*

<u>Day</u>	<u>Hours</u>
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.

Extended Wear (Overnight)

The suggested wearing schedule for the Menicon Z Contact Lens for extended wear is to initially adapt to daily wear during the first week of wear as described above. During the second week (Days 8-14), the patient should comfortably wear the lenses during all waking hours. Then;

<u>Day</u>	<u>Hours*</u>
15-21	24 hours a day, with an overnight removal every 7 days

* If the lenses continue to be well tolerated.

The maximum suggested wearing time for Menicon Z extended wear is 1 week (7 days). Lenses should be removed for cleaning and disinfecting for 8 - 10 hours (overnight) at the end of 1 week of extended wear, or more frequently depending on the overall patient tolerance.

CLINICAL ASSESSMENT :

- a. Vision should be crisp and clear after the blink.
- b. The eye should be white and quiet.

Temporary discomfort may be caused by a foreign body under the lens surface. The lens should be removed, rinsed and reinserted. If the discomfort persists, the patient should consult the eyecare professional before returning to lens wear.

MONOVISION FITTING GUIDELINES :**1. Patient Selection****A. Monovision Needs Assessment**

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient may not be a good candidate for monovision with the Menicon Z (tisilfocon A) Contact Lens. Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

- (1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- (2) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive this correction, OR may require that additional overcorrection be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "sight eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demand Method

Consider the patients' occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.

Example:

A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.25 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions are completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions.

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation.
- Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eyecare professional in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the Patient Instructions for Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lenses.

H A N D L I N G O F M E N I C O N Z C O N T A C T L E N S E S :

Conventional lens placement and removal applies to Menicon Z (tisilfocon A) contact lenses. Please instruct the patient how to place and remove the lens. Make sure that the patient is able to put on the lenses and remove them before the patient leaves your office.

P A T I E N T L E N S C A R E D I R E C T I O N S :

Eyecare 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 (To First Clean and Rinse, Then Disinfect Lenses)

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 eyecare professional) and disinfect lenses according to the schedule prescribed by the eyecare 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. Eyecare 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.
- Abrasive surfactant cleaners such as Boston®, Boston Advance® Opt-Free® and Opti-Soak® are not recommended for use with the Menicon Z lens.

Lens Care Table

Solution Purpose	Menicon/Allergan Claris® Gas Permeable Care System Chemical (not heat) disinfection
Cleaning	Claris® Cleaning and Soaking Solution
Rinsing	Lens Plus® Sterile Saline Solution or as recommended by your eye care professional
Disinfection/Storage	Claris® Cleaning and Soaking Solution
Lubrication/Rewetting	Claris® Rewetting Drops
Periodic Protein Cleaning	ProFree/GP Weekly Enzymatic Cleaner

Claris® and Lens Plus® are trademarks of Allergan, Inc.

- **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 mixups) 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 eyecare 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 eyecare professional for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the 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 eyecare professional.
- Eyecare 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 eyecare professional.
- Thoroughly rinse lenses with a fresh saline solution or other 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.

CARE FOR A STICKING (NONMOVING) 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 nonmovement of the lens continues after 10 minutes, the lens edge should be gently manipulated using the eyelid (Do not touch the lens directly), the patient should **immediately** consult the eyecare professional.

HOW SUPPLIED:

Each Menicon Z (tisilfocon A) Contact Lens is shipped non-sterile immersed in Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution (0.02% edetate disodium and 0.005% chlorhexidine gluconate as preservatives) in an individual plastic container. If the patient is sensitive to edetate disodium or chlorhexidine gluconate, 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.

Dry shipped lenses are available upon request.

The plastic container is marked with the information for base curve, diopter power, diameter, center thickness, color, UV-absorber, lot number, hydration date and other required parameters specified by the design.

LENS ORDERING:

To order Menicon Z (tisilfocon A) prescription lenses, please specify parameters. Call the manufacturer toll free at 1-800-MENICON.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing Menicon Z (tisilfocon A) lenses experienced with the lenses should be reported to:

Menicon U.S.A. Inc.
333 West Pontiac Way
Clovis, CA 93612
1-800-MENICON

**PATIENT
INSTRUCTIONS**

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

**CAUTION: Federal Law Prohibits Dispensing
Without a Prescription**

Menicon Z

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INTRODUCTION

The Menicon Z™ (tisilfocon A) Rigid Gas Permeable spherical and non-prism ballast toric contact lenses are intended for daily wear or extended wear. Prism ballast toric and bifocal lenses are for daily wear use only. The lens color is light blue with an ultraviolet absorber added (Benzotriazol).

NOTE: The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV-light has not been established at this time.

WEARING RESTRICTIONS AND INDICATIONS

Menicon Z (tisilfocon A) spherical or aspheric lenses are indicated for daily wear or extended wear (from 1 to 7 days between removals for cleaning and disinfection of the lenses, as recommended by the eyecare practitioner) for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

Menicon Z (tisilfocon A) toric and 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 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 eyecare professional.

IF YOU ARE ON A DAILY WEAR SCHEDULE, DO NOT WEAR YOUR MENICON Z™ CONTACT LENSES WHILE SLEEPING.

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 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:

uff

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that you follow your eyecare 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 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 these lenses are worn overnight.
- The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens users.
- If you experience **eye discomfort**, excessive tearing, vision changes, or redness of the eye, you should **immediately remove lenses** and promptly contact your eyecare 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.**

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 practitioner for more information.

PRECAUTIONS:

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

- Before leaving the eyecare professional's office, you should be able to promptly remove lenses or should have someone else available who can remove the lenses for you.
- Remove the lenses immediately if the eye becomes red or irritated.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - 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.]
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, **immediately** consult your eyecare professional.
- 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-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eyecare professional.
- Never wear lenses beyond the period recommended by your eyecare professional.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare professional about wearing lenses during water activities and other sports.
- Inform your doctor (health care professional) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use.
- Do not touch the lens with fingernails.
- Always contact your eyecare professional before using any medicine in the eyes.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- 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.

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

- 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 the eyecare 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 the eyecare professional.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. **Keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.**

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.
- 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 contact lens professional will outline a method that is most suitable for you, here's a standard procedure for placing and removing your lenses that you can always refer to:

- 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.

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 eyecare 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.

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eyecare 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, place the index finger of your right hand at the outer corner of the eyelid and look down into the palm of your left hand or into the center of a soft cloth place 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 this method of removing your lens is difficult for you, your eyecare 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 eyecare 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. **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 eyecare 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 eyecare 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 eyecare 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 RGP lenses. See Package Insert for other products that may be used with this lens. Your eyecare professional may recommend alternate solutions that are appropriate for you to use with your Menicon Z™ (tisilfocon A) 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

Solution Purpose	Menicon/Allergan Claris® Gas Permeable Care System; Chemical (not heat) disinfection
Cleaning	Claris® Cleaning and Soaking Solution
Rinsing	Lens Plus® Sterile Saline Solution or other solution recommended by your eye care professional
Disinfection/Storage	Claris® Cleaning and Soaking Solution
Lubrication/Rewetting	Claris® Rewetting Drops
Periodic Protein Cleaning	ProFree/GP Weekly Enzymatic Cleaner

Claris® and Lens Plus® are trademarks of Allergan, Inc.

- **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 eyecare 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 eyecare 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 eyecare professional for a recommendation on how to store your lenses.
- Menicon Z (tisilfocon A) Contact Lenses cannot be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; 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 eyecare 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.

2. Care for a Sticking (Nonmoving) 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 nonmovement of the lens continues after 10 minutes, you should immediately consult your eyecare 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 eyecare 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 eyecare 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 eyecare 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 solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare 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 AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYECARE PRACTITIONER 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 eyecare 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 eyecare professional.
- It is important that you follow your eyecare professional's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and affect the adaptation period.
- The decision to be fit with a monovision correction is most appropriately left to the eyecare professional in conjunction with you, after carefully considering and discussing your needs.

WEARING AND APPOINTMENT SCHEDULES

YOUR WEARING SCHEDULE SHOULD BE DETERMINED BY YOUR EYECARE PRACTITIONER.

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

The maximum suggested wearing time for the Menicon Z™ (tisilfocon A) lens is:

Daily Wear (During Waking Hours)*

<u>Day</u>	<u>Hours</u>
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.

Extended Wear (Overnight)

The suggested wearing schedule for the Menicon Z Contact Lens for extended wear is to initially adapt to daily wear during the first week of wear as described above. During the second week (Days 8-14), the patient should comfortably wear the lenses during all waking hours. Then;

<u>Day</u>	<u>Hours*</u>
15-21	24 hours a day, with an overnight removal every 7 days

* If the lenses continue to be well tolerated.

The maximum suggested wearing time for Menicon Z extended wear is 1 week (7 days). Lenses should be removed for cleaning and disinfecting for 8 - 10 hours (overnight) at the end of 1 week of extended wear, or more frequently depending on the overall patient tolerance.

Prescribed Wearing Schedule

<u>Day</u>	<u>Wearing Time (Hours)</u>
1	_____
2	_____
3	_____
4	_____
5	_____
6 and after	_____

Appointment Schedule

Your appointments are on				Minimum number of hours lenses to be worn at time of appointment
Month	Year	Time	Day	
_____	_____	_____	_____	
_____	_____	_____	_____	
_____	_____	_____	_____	
_____	_____	_____	_____	

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PATIENT/EYECARE PROFESSIONAL INFORMATION:

Eyecare Professional Information

Eyecare Professional Name: _____
Practice Name: _____
Eyecare Professional Address: _____
Eyecare Professional Phone Number: _____
Recommended Lens Care Regimen: _____
Cleaning Solution: _____
Rinsing Solution: _____
Disinfecting Solution: _____
Lubricating Solution: _____

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 EYECARE PRACTITIONER IMMEDIATELY.

Menicon

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Clovis, California 93612

1-800-MENICON (1-800-636-4266)

March 1999

PACKAGE INSERT

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

CAUTION: Federal Law Prohibits Dispensing Without a Prescription.

Menicon Z™ (tisilfocon A)

Rigid Gas Permeable Contact Lenses

Spherical and Aspherical Lenses for Myopia and Hyperopia
Toric Lenses to Correct Astigmatism
Multifocal Lenses for Presbyopia
in Aphakic and Not-Aphakic Persons

DESCRIPTION:

The Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lens is available as a daily wear spherical, aspheric, prism ballast toric or multifocal design and as an extended wear spherical, non-prism ballast toric and aspheric design.

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 light blue tint. The 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.

NOTE: The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV-light has not been established at this time.

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 Aspherical lens:

Diameter	7.0 to 12.0 mm
Center Thickness	0.08 to 0.50 mm
Base Curve	6.50 to 9.00 mm (in 0.05 mm steps)
Powers	-25.00 to +20.00 D (in 0.25 D steps)
	-20.00 to +12.00 D (in 0.25 D steps) (extended wear)

Toric lens:	
Diameter	7.0 to 11.0 mm
Center Thickness	0.08 to 0.50 mm
Base Curve	7.30 to 8.50 mm
Sphere Powers	-10.00 to +10.00 D (in 0.25 D steps)
Cylinder Powers	-0.50 to -5.00 D (in 0.25 D steps)
Prism Ballast	0.75 to 2.00 D (in 0.25D steps)
Truncation Height	0.0 to 1.0 mm (in 0.1 mm steps)

Multifocal Lens (Concentric, De-centered, Crescent):	
Diameter	8.0 to 11.0 mm
Center Thickness	0.08 to 0.65 mm
Base Curve	7.30 to 8.50 mm
Sphere Power	+6.00 to -10.00 D
Add Power	+0.75 to +3.00 D

The physical/optical properties of the lens are:

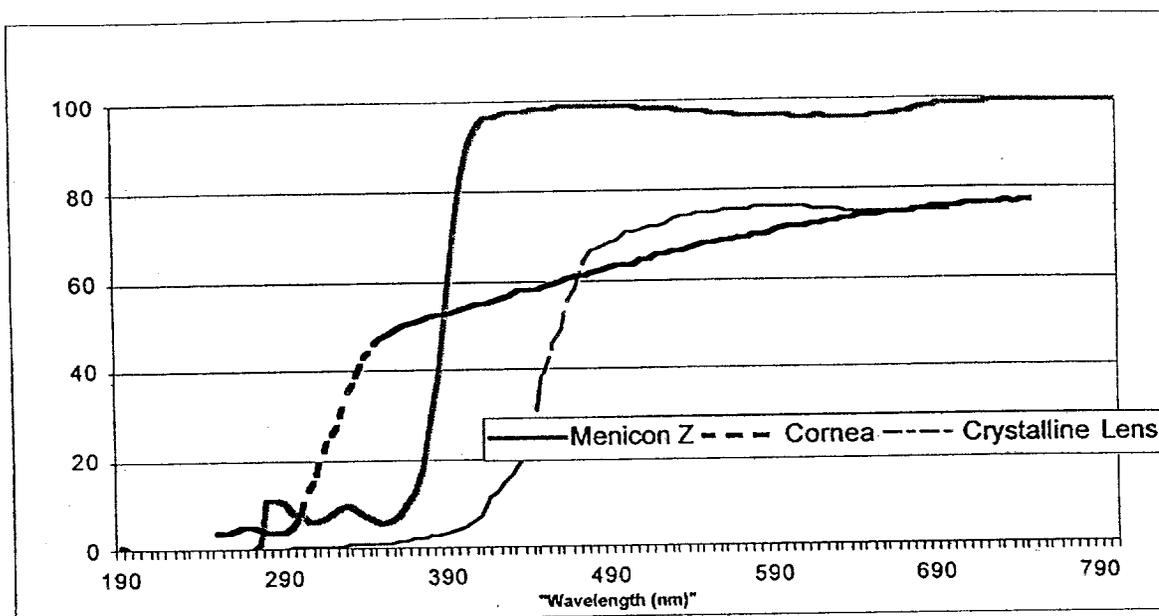
Specific Gravity:	1.20
Refractive Index:	$n_D^{25} 1.436 \pm 0.001$
Surface Character:	Hydrophobic
Wetting Angle:	24 degrees (after soaking)
Light Transmittance:	Visible region: > 95% (380 nm - 780 nm) Ultraviolet region: < 6% (210 nm - 380 nm)

Water Absorption:	(sample thickness 0.08mm) Less than 0.5% by weight
Oxygen Permeability:	$163 \times 10^{-11} \text{ (cm}^2/\text{sec)(mL O}_2\text{/(mL x mmHg) Dk}^*$ $189 \times 10^{-11} \text{**}$ $250 \times 10^{-11} \text{***}$

* 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)



MENICON Z RGP - Spectral transmittance curve for Menicon Z (tisilfocon A) Contact Lens - D & C Green No. 6 and UV absorbing agent (sample thickness Menicon Z lens polymer plate = 0.08 mm, 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.

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 rigid gas permeable contact lens is a lathe cut firm contact lens with spherical or aspherical 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 Toric Contact Lens provides a more even surface over the differing curvatures of the astigmatic cornea and thus helps to focus light rays on the retina.

The Menicon Z Multifocal Contact Lens provides the necessary optical powers to correct different refractive errors for distance and near requirements.

INDICATIONS (USES):

Menicon Z (tisilfocon A) spherical, aspheric, prism ballast, toric and 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.

Menicon Z (tisilfocon A) spherical or aspheric lenses and non-prism ballast toric lenses are indicated for extended wear (from 1 to 7 days between removals for cleaning and disinfection of the lenses, as recommended by the eyecare practitioner) for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in non-aphakic persons with non-diseased eyes.

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

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 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 patients follow their eyecare 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 are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens

- 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 eyecare 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.

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 practitioner for more information.

PRECAUTIONS:

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

Special Precautions for Eyecare Professionals:

- Lenses are shipped in a vial immersed in Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution. If the vial has missing solution or is dry, return the product to Menicon according to Menicon return policies.
- If continual wet storage of wet shipped contact lenses is preferred, the Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution should be changed every 30 days from the hydration date.
- If the patient is sensitive to edetate disodium or chlorhexidine gluconate, 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.
- 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 design and parameters, the eyecare professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare professional.

- Aphakic and other post-surgical persons should not be fitted with Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eyecare 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.

- Eyecare 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 contact lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)
- 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.

Eyecare professionals should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
 - Always use fresh unexpired lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - 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.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 - Always keep the lenses completely immersed in 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.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eyecare professional.
- 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-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the Menicon Contact Lens and those prescribed by the eyecare professional.
- Never wear lenses beyond the period recommended by the eyecare professional.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare professional about wearing lenses during water activities and other sports.
- Inform the doctor (health care professional) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use.
- Do not touch the lens with fingernails.
- Always contact the eyecare professional before using any medicine in the eyes.
- 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.
- 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.

ADVERSE REACTIONS:

The patient should be informed that 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
- 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 eyecare 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 eyecare professional.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

PREPARING AN RGP LENS FOR FITTING

Menicon Z (tisilfocon A) Contact Lenses should be thoroughly cleaned with the recommended cleaning solution and hydrated in the desired soaking/conditioning solution for at least 4 hours prior to placement on the eye to insure maximum surface wettability.

FITTING:

Conventional methods of fitting contact lenses apply to Menicon Z (tisilfocon A) Contact Lenses. 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:

Menicon U.S.A. Inc.
333 West Pontiac Way
Clovis, CA 93612
1-800-MENICON

WEARING SCHEDULE:

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

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

Daily Wear (During Waking Hours)*

<u>Day</u>	<u>Hours</u>
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.

Extended Wear (Overnight)

The suggested wearing schedule for the Menicon Z Contact Lens for extended wear is to initially adapt to daily wear during the first week of wear as described above. During the second week (Days 8-14), the patient should comfortably wear the lenses during all waking hours. Then;

<u>Day</u>	<u>Hours*</u>
15-21	24 hours a day, with an overnight removal every 7 days

* If the lenses continue to be well tolerated.

The maximum suggested wearing time for Menicon Z extended wear is 1 week (7 days). Lenses should be removed for cleaning and disinfecting for 8 - 10 hours (overnight) at the end of 1 week of extended wear, or more frequently depending on the overall patient tolerance.

LENS CARE DIRECTIONS:

Note: Abrasive surfactant cleaners such as Boston®, Boston Advance®, Opti-Free® and Opti-Soak® should not be used.

Eyecare 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, rinse, and dry 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 eyecare professional) and disinfect lenses according to the schedule prescribed by the eyecare 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. Eyecare 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	Menicon/Allergan Claris® Gas Permeable Care System; Chemical (not heat) disinfection
Cleaning	Claris® Cleaning and Soaking Solution
Rinsing	Lens Plus® Sterile Saline Solution or other solution as recommended by your eye care professional
Disinfection/Storage	Claris® Cleaning and Soaking Solution
Lubrication/Rewetting	Claris® Rewetting Drops
Periodic Protein Cleaning	ProFree/GP Weekly Enzymatic Cleaner

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ALTERNATE CARE SYSTEMS:

	Lens Care Table
Cleaning	Optimum by LoBob® Cleaning, Disinfecting and Storage Solution
Rinsing	Rinsing Solution as Recommended by Eyecare Professional
Disinfection/Storage	Optimum by LoBob® Cleaning, Disinfecting and Storage Solution
Lubrication/Rewetting	Optimum by LoBob® Wetting/Rewetting Drop and In-the-Eye Lubricant
Periodic Cleaner	Optimum by LoBob® Extra Strength Cleaner

	Lens Care Table
Solution Purpose	Barnes-Hind® Comfort Care® Gas Permeable Care System Chemical (not heat) disinfection
Cleaning	Barnes-Hind® Comfort Care® GP Dual Action Daily Cleaner
Rinsing	Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution
Disinfection/Storage	Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution
Lubrication/Rewetting	Barnes-Hind® Comfort Care® Comfort Drops

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- 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 eyecare 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 eyecare professional for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the 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 eyecare professional.
- Eyecare 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 eyecare 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 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 (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 eyecare 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. 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 eyecare 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.

LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens manufacturer or your eyecare professional.

CARE FOR A STICKING (NONMOVING) 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 nonmovement of the lens continues after 10 minutes, the patient should immediately consult the eyecare 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 EYECARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

Each Menicon Z (tisilfocon A) Contact Lens is shipped non-sterile immersed in Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution (0.02% edetate disodium and 0.005% chlorhexidine gluconate as preservatives) in an individual plastic container. If the patient is sensitive to edetate disodium or chlorhexidine gluconate, 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.

Dry shipped lenses are available upon request.

The plastic container is marked with the information for base curve, diopter power, diameter, center thickness, color, UV-absorber, lot number, 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 experienced with the lenses should be reported to:

Menicon U.S.A. Inc.
333 West Pontiac Way
Clovis, CA 93612
1-800-MENICON (1-800-636-4266)