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 (U.S.A) law restricts this device to sale by or on the order of a licensed eyecare professional.

Menicon Z™ (tisilfocon A)

Rigid Gas Permeable Contact Lenses

Spherical and Aspheric Lenses for Myopia and Hyperopia
Toric Lenses to Correct Astigmatism
Multifocal Lenses for Presbyopia
in Aphakic and Non-Aphakic Persons

DESCRIPTION:
The Menicon Z™(tisilfocon A) Rigid Gas Permeable Contact Lens is available as a daily wear spherical, aspheric, prism ballast toric or multifocal design and as an extended wear lens for up to 30 days/29 nights in spherical, aspheric, non-prism ballast toric and multifocal designs.

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

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

Spherical and Aspheric Lens:	
Diameter	7.0 to 12.0mm
Center Thickness	0.08 to 0.50mm (daily wear)
	0.08 to 0.38mm (extended wear)
Base Curve	6.50 to 9.00mm
Powers	-25.00 to +25.00D (in 0.25D steps) (daily wear)
	-25.00 to +8.00D (in 0.25D steps) (extended wear)

Toric lens:	
Diameter	7.0 to 11.0mm
Center Thickness	0.08 to 0.50mm (daily wear)
	0.08 to 0.38mm (extended wear)
Base Curve	7.30 to 8.50mm
Sphere Powers	-10.00 to +8.00D (in 0.25D steps)
Cylinder Powers	-0.50 to -5.00D (in 0.25D steps)
Prism Ballast	0.75 to 2.00D (in 0.25D steps) (daily wear only)
Truncation Height	0.0 to 1.0mm (in 0.1mm steps) (daily wear only)

Multifocal Lens (Centered, Decentered, Crescent):

Diameter	8.8 to 11.0mm
Center Thickness	0.08 to 0.65mm (daily wear)
	0.08 to 0.38mm (extended wear)
Base Curve	7.00 to 9.00mm
Sphere Power	-13.00 to +5.00D
Add Power	+1.00 to +3.00D

The physical/optical properties of the lens are:

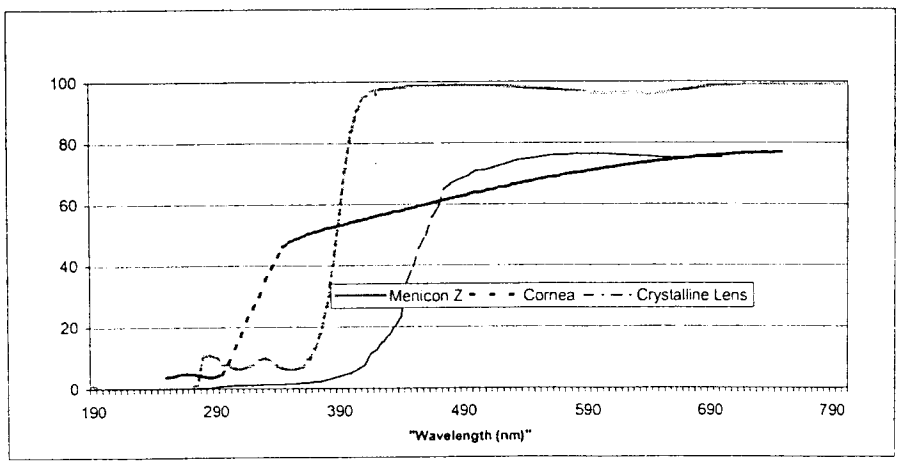
Specific Gravity:	1.20
Refractive Index:	n^{25}_D 1.436± 0.001
Surface Character:	Hydrophobic
Wetting Angle:	24 degrees (after soaking)
Light Transmittance:	Visible region >95% (380 nm – 780 nm)
	Ultraviolet region <6% (210 nm – 380 nm)
	(sample thickness 0.08mm)
Water Absorption:	Less than 0.5% by weight
Oxygen Permeability:	$163x10^{-11}$ (cm^2/sec)(mL O_2/(mL x mmHg)) Dk*
	$189x10^{-11}$**
	$250x10^{-11}$***

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

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

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

WAVELENGTH nm



Menicon Z™ (tisilfocon A) Contact Lens - Spectral transmittance curve for Menicon Z™ (tisilfocon A) Contact Lens - D & C Green No. 6 and UV absorbing agent (sample thickness Menicon Z™ (tisilfocon A) lens polymer plate = 0.08mm, representing the thinnest marketed version of the lens).
CORNEA - Human cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, P. 58, figure 2-21.
CRYSTALLINE LENS - Human crystalline lens from a 25-year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

Note: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult the eyecare professional for more information.

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

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

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

INDICATIONS (USES):

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

Menicon Z™ (tisilfocon A) spherical, aspheric, non-prism ballast toric and non-prism ballast multifocal lenses are indicated for extended wear (from 1 to 30 days between removals for cleaning and disinfection of the lenses, as recommended by the eyecare professional) for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in non-aphakic persons with non-diseased eyes.

The lens may be prescribed in spherical and aspheric powers ranging from -25.00 D to +25.00 D for daily wear and -25.00 D to +8.00 D for up to 30 days extended wear. Toric lenses are designed to correct up to 5.00 D of astigmatism and multifocal lenses to provide up to +3.00 D of reading add power for up to 30 days extended wear.

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

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

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the Menicon Z™(tisilfocon A) Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior segment of the eye
- Any eye disease, injury, or abnormality 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.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping.[1,2]
- 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. The long-term risk of microbial keratitis has not been determined for this lens when worn for greater than 7 days extended wear. Postmarketing studies are in progress to evaluate the risk up to 30 days.
- 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.**

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

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

PRECAUTIONS:

CAUTION: NON-STERILE. ALWAYS CLEAN AND DISINFECT LENSES PRIOR TO USE.

Special Precautions for Eyecare Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens and wear schedule for a patient, the eye care professional should consider all lens characteristics that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

  Lens designs with an average thickness over the central 6 mm greater than 0.19 mm (Rx outside the range of –0.25 to –15.00 in thin lens designs) do not provide oxygen transmissibility above the established threshold level required to prevent overnight corneal edema[3]. Thin lens designs should always be considered when fitting patients for extended wear. Deswelling rates with RGP lenses have been shown to be rapid and nearly complete within the first three hours of awakening. The prescribing eye care professional should carefully assess the potential impact of these factors and carefully monitor the continuing ocular health of the patient and lens performance on the eye.
- 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.
- The following patients may not be suitable extended wear contact lens candidates, and/or may experience a higher rate of adverse effects associated with contact lens wear:
  - ◊ Patients with a history of acute inflammatory reactions to contact lens wear.
  - ◊ Patients with a history of giant papillary conjunctivitis associated with contact lens wear.
  - ◊ Patients with a history of ocular allergies may need to temporarily discontinue lens wear during certain times of the year.
  - ◊ Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule, or follow-up visit schedule.
  - ◊ Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.
  - ◊ Patients who are unwilling or unable to adhere to a recommended care regimen, or who are unable to insert and remove lenses, should not be provided with them.
- 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™ (tisilfocon A) Contact Lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)
- Some patients will not be able to tolerate continuous wear even if able to tolerate the same or another lens on a daily wear basis. Some patients who are able to tolerate continuous wear will not be able to wear their lenses continuously for 30 days. Patients should be carefully evaluated for continuous wear prior to prescription and dispensing, and eyecare professionals should conduct early and frequent follow-up examination to determine ocular response to continuous wear.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic and other post-surgical persons should not be fitted with Menicon Z™ (tisilfocon A) Contact Lenses until the determination is made that the eye has healed completely.

[3]Investigative Ophthalmology and Visual Science, October 1984; Vol 25, pp. 1161-1167

- Lenses are shipped in a plastic container immersed in Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution. If the plastic container has missing solution or is dry, return the product to the Authorized Manufacturing Lab according to their 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.
- 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. It is strongly recommended that patients be provided with a copy of the Patient Instructions for the Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lens available from Menicon and understand its contents prior to dispensing the lenses.

Handling Precautions:

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

Solution Precautions:

- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may reduce the ability of the lens surface to return to a wettable state.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Do not heat the cleaning, wetting, and/or soaking solution and lenses. Keep away from extreme heat.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the Menicon Z™ (tisilfocon A) Contact Lenses.

Lens Wearing Precautions:

- Never wear lenses beyond the period recommended by the eyecare professional.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Non-Moving) Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eyecare professional.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions:

- Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with 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.

Topics to Discuss with the Patient:

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

Who Should Know That the Patient is Wearing Contact Lenses:

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

ADVERSE REACTIONS:
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
- Abnormal feeling that something is in the eye such as a foreign body or scratched area
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the 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.**

If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient **should immediately remove the lenses and contact his or her eyecare professional** or physician, who must determine the need for examination, treatment or referral without delay (See Important Treatment Information for Adverse Reactions). A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

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

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

PREPARING 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.

CLINICAL STUDY RESULTS:

Study Description:

Six hundred sixty-one (661) subjects were enrolled into a pre-market clinical trial at 24 investigational sites throughout the United States of America. Of those, 630 subjects were determined to be evaluable.

This trial was a multi-center, prospective, open-label, concurrent cohort controlled clinical trial with subjects followed for up to one year. Subjects were assigned either the Menicon Z™ RGP contact lenses or the control soft (hydrophilic) contact lenses based upon their previous lens experience. A total of 317 evaluable Test subjects (Menicon Z) and 313 evaluable Control subjects were recruited. Subjects wore their assigned lenses bilaterally for the duration of the trial.

The Test and the Control lenses were worn on a daily wear schedule for at least 2 weeks prior to advancing to the extended (continuous wear) schedule. The extended wearing schedule for the Test lenses was up to 30 days/29 nights of continuous wear. The Control lenses were worn on an extended wear schedule of up to 7 days/6 nights of continuous wear. The Test subjects replaced their lenses only when needed for cause. The Control subjects replaced their lenses on a weekly basis.

A total of 258 Test subjects (516 eyes) and 210 Control subjects (420 eyes) completed the study. Fifty-nine (59) of the Test subjects (118 eyes) and 103 of the Control subjects (205 eyes) discontinued from the study.

Subject Assessments

Subjects were evaluated upon enrollment to determine eligibility, then scheduled for a dispensing visit. Once dispensed the lenses, subjects were instructed to wear their lenses on a daily wear basis until the 2 week visit, at which time they were evaluated to determine if they could begin extended wear. Once extended wear was initiated, the subjects were evaluated at an optional 24-72 hour visit, and then at the 1 week, 1 month, 3 month, 6 month, 9 month and 12 month visits.

Demographic Data

The Test and the Control groups were similar in regard to gender, medication use, proportion of smokers and average daily wearing time. Differences between the groups are related to the differences in the overall population of rigid gas permeable (RGP) and soft contact lens (SCL) wearers. The Test (RGP) lens subjects were significantly older (an average of 6 years) with a longer history of contact lens wear as compared to the Control (SCL) lens subjects. All subjects recruited were adapted full-time daily wearers of the appropriate lens modality who had no previous extended wear experience.

Gender distribution was similar between the Test and the Control cohorts with a female to male ratio of 2.7 to 1 for the Test cohort and 2.8 to 1 for the Control cohort.

DATA ANALYSIS AND RESULTS

The study was designed to evaluate the equivalence of the Test lens when worn on an extended wear basis for up to 30 days/29 nights to the Control lens when worn on an extended wear basis for up to 7 days/6 nights.

Primary Safety Endpoints

The primary safety endpoint analysis was based upon a comparison between the Test and the Control cohorts of the proportion of visual acuity changes and slit lamp findings.

Visual acuity change criteria included:

- Reductions of best corrected visual acuity (BCVA) by 2 or more Snellen lines from the dispensing BCVA; or
- a decrease in BCVA to worse than 20/40.

The analysis of slit lamp findings as safety criteria is based on the following 5 signs:

- infiltrates of grade 3 or 4;
- corneal staining of grade 3 or 4;
- corneal edema of grade 3 or 4
- giant papillary conjunctivitis (GPC) of grade 3 or 4;
- neovascularization of more than 1.5 mm in a single quadrant or more than 1.0 mm in multiple quadrants

The analysis of the study results indicated no significant difference between the Test lenses and the Control lenses in respect to the safety endpoints. One (1) completed Test subject had one incidence of a decrease in BCVA in the right eye that subsequently returned to the baseline BCVA. Twenty (20) subjects in the Test cohort (6.3%) and 16 subjects in the Control cohort (5.1%) met the slit lamp criteria in either eye at any of their study visits. These percentages were not statistically significantly different ($p=0.50$). The event rate (event in either eye) for the Test cohort was 11.8 per 1000 patient visits and for the Control cohort was 10.8 per 1000 patient visits. This event rate is not statistically different ($p=0.70$).

The Test lens was found to be statistically equivalent to the Control lens in terms of the safety endpoints.

Secondary Safety Endpoints

For all grades of slit lamp findings, extended wear was associated with higher rates of positive findings than daily wear in several categories. The percentages of positive findings for these categories throughout the extended wear phase of the study are as follows: epithelial microcysts (1.6% in Test, 7.0% in Control), epithelial edema (1.1% Test, 3.6% Control), stromal edema (0.3% Test, 1.1% Control), corneal staining (12.4% Test, 17.4% Control), and 3 & 9 o'clock staining (22.2% Test, 0.4% Control).

In both daily and extended wear, neovascularization and palpebral conjunctival abnormalities were noted more often in soft lens wearers, with 3 & 9 o'clock staining noted more often in RGP lens wearers.

Primary Efficacy Endpoints

Efficacy endpoints were set as the percentage of subjects achieving and maintaining the targeted extended wearing time schedule of 30 days/29 nights for the Test cohort and 7 days/6 nights for the Control cohort. Completion of the study was defined as completion of the 12 month follow-up period with the appropriate evaluations performed.

Average Wearing Time

Average wearing times of 22 days or more were reported at 66.5% of all visits after 1 month. 15.5% of wearing time reports were for periods of 8-21 days and 18% of wearing time reports were for periods of less than 8 days.

Adverse Effects

Sixty-three adverse events were reported during the clinical study. Of these, 27 were reported for the Test cohort and 36 were reported for the Control cohort. The events are shown by type in the following table (the columns headed "Subjects" present the number of subjects with a specific Adverse Event as a proportion of the total subjects in each cohort).

Adverse Events by Type
All Test and Control Subjects

	Subjects	
CORNEAL ADVERSE EVENTS	**Test**	**Control**
Inflammatory/Infectious Events		
Infiltrative Keratitis	0.3%	2.6%
Vascularized Limbal Keratitis	0.6%	0.0%
Corneal Ulcers	0.3%	0.3%
Abrasions		
Foreign Body	2.8%	0.3%
Metabolic	0.0%	0.3%
Unknown	0.0%	0.6%
Chemical	0.3%	0.3%
Edema		
Microcystic	0.0%	0.3%
CONJUNCTIVAL ADVERSE EVENTS		
Bacterial	0.6%	2.9%
Viral	0.3%	0.0%
Allergic	1.3%	0.6%
GPC	0.3%	0.6%
Unknown	0.3%	0.6%
MISCELLANEOUS ADVERSE EVENTS		
Sinus Infection	0.0%	0.3%
Trauma	0.0%	0.3%
Lens Displacement	0.0%	0.3%
Neurological	0.0%	0.3%
Episcleritis	0.3%	0.3%
Lacrimal Occlusion	0.3%	0.0%
Lens Awareness	0.3%	0.0%
Total Subjects	**317**	**313**

There were 18 reports of lens adherence for the Test group. These 18 reports were for 10 subjects/16 eyes.

Discontinued Subjects
There were 59 Test subjects and 103 Control subjects discontinued during the 12 month clinical. The reasons for discontinuation were as follows:

Reasons for Discontinuation By Cohort

	Test Subjects	Control Subjects
Subjects Enrolled	317	313
Lost to Follow-up	3.8%	9.3%
Protocol Violation	2.8%	6.7%
Comfort	3.8%	5.1%
Subject Decision	4.1%	3.5%
Positive Slit Lamp Findings:		
Related to Study Lens	0.9%	2.6%
Unrelated to Study Lens	0.0%	0.3%
Adverse Event	0.9%	2.2%
Investigator Decision	1.3%	1.3%
Unacceptable Visual Acuity	0.0%	0.3%
Other:	0.9%	1.6%

There were 3 Test subjects and 9 Control subjects discontinued for Positive Slit Lamp Findings. The 3 Test subjects were discontinued for epithelial hypertrophy at 3&9 o'clock, increased neovascularization, and limbal desiccation. The 9 Control subjects discontinued for Positive Slit Lamp Findings were discontinued for neovascularization, microcysts/edema, GPC, and infiltrates.

There were 3 Test subjects and 7 Control subjects discontinued for Adverse Event. The 3 Test subjects were discontinued for epithelial corneal defect, allergic reaction, and marginal ulcerative keratitis. The 7 Control subjects were discontinued for microcystic edema, multiple incidents of keratitis, acute ocular inflammation, sector field defect, corneal ulcer, and infiltrative keratitis.

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:

Authorized Manufacturing Lab
Street Address
City, State Zip
Telephone Number

WEARING SCHEDULE:

The wearing schedule should be determined by the eyecare professional. Not all patients can achieve the maximum wear time of up to 30 days of continuous wear. Patients should be monitored closely during the first month of 30-day continuous wear. **If problems occur during this first month, the patient may not be suitable for the full 30-day wearing schedule.** The maximum suggested wearing time should be determined by the eyecare professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. Regular check-ups, as determined by the eyecare professional, are extremely important.

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)*

Day	Hours
1	4-8
2	6-10
3	8-14
4	10-15
5	12-all waking hours
6 and after -	all waking hours

* If the lenses continue to be well tolerated.
Lenses should be removed daily for cleaning and disinfecting (according to lens care system instructions) before wearing.

Extended Wear (Overnight)*

- **Lens Designs Approved for extended wear range from +8.00 to –25.00D. Prism ballast designs are not approved for extended wear.**
- **It is suggested that new contact lens wearers first be evaluated on a daily wear schedule. If the patient is judged to be an acceptable extended wear candidate, the eyecare professional may determine an extended wear schedule based upon the response of the patient.**
- The eyecare professional should establish an extended wear period up to a maximum of 30 continuous days/29 nights that is appropriate for each patient. Once the lenses are removed, the patient's eyes should have a rest period with no lens wear of overnight or longer, as recommended by the eyecare professional.
- See **WARNINGS** for information about the relationship between wearing schedule and corneal complications and **CLINICAL RESULTS** for important information about average wear times and other study findings.

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 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.

RECOMMENDED CARE SYSTEM:

LENS CARE TABLE

Solution Purpose	**Menicon/Allergan Claris® Gas Perm 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

ALTERNATE CARE SYSTEMS:

LENS CARE TABLE

Solution Purpose	**Optimum by Lobob®** Chemical (not heat) disinfection
Cleaning Solution	Optimum by Lobob® Cleaning, Disinfecting and Storage
Rinsing	Rinsing solution as recommended by eye care 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

Optimum by Lobob® is a trademark of Lobob® Laboratories, Inc.

LENS CARE TABLE

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

Barnes-Hind® and Comfort Care® 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) 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 and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- **Caution**: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution (or follow the instructions on the disinfection solution labeling) prior to placement on the eye should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:
Enzyme cleaning may be recommended by the 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.

CARE FOR A STICKING (NON-MOVING) LENS:
If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If 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™ (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 plastic container upon receipt, rinsed with fresh saline solution, cleaned with a cleaner and placed in another prescribed disinfecting solution prior to dispensing. Follow the manufacturer's instructions on the disinfecting solution label.

Dry shipped lenses are available upon request.

The plastic container 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 should be reported to:

Authorized Manufacturing Lab
Street Address
City, State Zip
Telephone Number

Menicon *Z*™

06/02 FRS

CONTAINER LABEL

Menicon Z™ (tisilfocon A)

[Light Blue], UV absorption

One RGP Contact Lens for Daily or Extended Wear immersed in Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution (0.02% edetate disodium and 0.005% chlorhexidine gluconate as preservatives). For continual wet storage of the lens, the Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution should be changed every 30 days from the hydration date.

Caution: Non-sterile. Clean and condition lenses prior to use.
Federal law prohibits dispensing without a prescription

Manufactured by: Authorized Manufacturing Lab.
City, State, Zip

B.C.
P.

DIA.

C.T.

LOT

Hydration Date:

Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lenses for Extended Wear

IMPORTANT: The following basic Information about contact lens wear and Menicon Z™ (tisilfocon A) lenses is provided for you by Menicon America, Inc.

If you are interested in Menicon Z™ (tisilfocon A) lenses, please see a licensed eye care professional. Based on your individual needs, your eye care professional will determine if Menicon Z lenses are right for you and how many days and nights you can wear them.

What are Menicon Z™ Contact Lenses?
Menicon Z lenses are Rigid Gas Permeable (RGP) contact lenses made of tisilfocon A material, a fluoro-methacrylate and siloxanylstyrene material that contains less than 0.5% water . This new lens material provides a high level of oxygen to your eyes.

How are Menicon Z RGP Contact Lenses used?
The lenses are worn on the cornea (front part of the eye) and used to correct vision by refocusing light rays onto the retina (back part of the eye).

The lenses may be used to correct nearsightedness (myopia) or farsightedness (hyperopia).astigmatism and presbyopia
They may be prescribed for:
Daily wear use - worn only while you are awake
Extended wear use - worn while you are awake and asleep
They may be worn for up to 30 days/29 nights (one month) of continuous wear based on how your eyes respond to lens wear and your eye care professional's recommendation.

Can everyone wear Menicon Z RGP Contact Lenses for 30 days/29 nights of continuous wear?
Not everyone can reach the maximum wear time of 30 continuous days/29 nights. During the U.S. clinical study, 516 of the 634 eyes dispensed completed the full year of lens wear, with the following success. Average wearing times of 22 days or more were reported at 66.5% of all visits after 1 month. 15.5% of wearing time reports were for periods of 8-21 days and 18% of wearing time reports were for periods of less than 8 days.

Your eye care professional may recommend a shorter wearing time depending on your individual needs, and you should always adhere to his or her recommendations. Once lenses are removed, your eyes should have a rest without lens wear for at least one overnight.

I already wear Menicon Z lenses. Can I now increase my wearing time to 30 days?
No. You must consult with your eye care professional first. Based on your specific needs, your eye care professional will recommend a wearing schedule for you.

Who should not wear contact lenses?
You should not wear contacts if you: Have an eye infection or inflammation (redness & swelling); Have an eye disease, eye injury or dryness that interferes with contact lens wear; Have a systemic disease that may be affected by or impact lens wear; Have certain types of allergic conditions; Are using certain medications, such as some eye medications.

What are the risks of wearing contact lenses for extended wear?
While there are many benefits of wearing contacts, sometimes problems can occur and the risk of serious problems is greater when lenses are worn for extended wear. You should carefully discuss the benefits and risks of extended wear lenses with your eye care professional.

There is an increased risk of developing a serious ocular infection, such as a corneal ulcer. A corneal ulcer may develop rapidly and cause eye pain, redness or blurry vision as it progresses. If left untreated, a scar, and in rare cases loss of vision, may result.
In addition, studies have shown that smoking increases the risk of corneal ulcers for those who wear lenses overnight.

What are other possible side effects of extended wear contact lenses?
An inflammation of the cornea called infiltrative keratitis is another potential side effect. During the one-year U.S. study about 0.6% of the 317 subjects experienced this type of side effect. In total, about 6.0 % of the subjects experienced one or a combination of moderate or severe events, including superficial corneal changes, corneal swelling or changes to the eyelid lining.

Are there times when you should not wear contact lenses?
Your eye care professional can tell you about situations or environmental conditions that may be inappropriate for contact lens wear. Some examples are: Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms; Fumes, smoke or vapors should be avoided to reduce the chance of lens contamination.

How often do I replace the lenses and how do I care for them?
Lenses should be replaced approximately once a year or as recommended by the eye care professional. When removed from your eyes in between wearing times they should be cleaned and disinfected with a chemical disinfection system (not heat). For convenience, it is recommended that you have a second pair of lenses on hand at all times.

What are some Important things to remember?
While wearing contacts your eyes should look well, feel comfortable and vision should be clear.
If you have a problem, Immediately remove your lenses and contact your eye care professional.

- Carefully follow your eye care professional's instructions for lens wear, care and replacement.
- **Never wear your lenses for longer periods than prescribed for you**
- See your eye care professional for follow-up care and periodic checkups.

What If I have other questions about Menicon Z RGP Contact Lenses?
It Is essential to see and talk with your eye care professional about your eye health and to obtain complete information about Menicon Z lenses. If you have questions, discuss them with your eye care professional.

If you want to read more about Menicon Z RGP Contact Lenses, ask your eye care professional for the Patient Instructions booklet available from Menicon America, Inc. or the Package Insert written for the eye care professional.

For more information contact your eye care professional or call 1-800-MENICON (1-800-636-4266).

Menicon Z material is marketed by
Menicon America, Inc.
San Mateo Gateway Center
1840 Gateway Drive Second Floor
San Mateo, CA 94404

PROFESSIONAL FITTING

AND

INFORMATION GUIDE

Menicon Z™ (tisilfocon A)

Rigid Gas Permeable Contact Lenses

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

Menicon Z™ (tisilfocon A)

TABLE OF CONTENTS

Authorized Manufacturing Lab
Street Address
City, State Zip
Telephone Number

INTRODUCTION

The Menicon Z™ (tisilfocon A) 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 prism ballast multifocal design and as an extended wear lens for up to 30 days/29 nights in spherical, aspheric, non-prism ballast toric and non-prism ballast multifocal designs.

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.

LENS PARAMETERS AVAILABLE

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

Spherical and Aspheric Lens:

Diameter	7.0 to 12.0mm
Center Thickness	0.08 to 0.50mm (daily wear)
	0.08 to 0.38mm (extended wear)
Base Curve	6.50 to 9.00mm
Powers	-25.00 to +25.00D (in 0.25D steps) (daily wear)
	-25.00 to +8.00D (in 0.25D steps) (extended wear)

Toric Lens:

Diameter	7.0 to 11.0mm
Center Thickness	0.08 to 0.50mm (daily wear)
	0.08 to 0.38mm (extended wear)
Base Curve	7.30 to 8.50mm
Sphere Powers	-10.00 to +8.00D (in 0.25D steps)
Cylinder Powers	-0.50 to -5.00D (in 0.25D steps)
Prism Ballast	0.75 to 2.00D (in 0.25D steps) (daily wear only)
Truncation Height	0.0 to 1.0mm (in 0.1mm steps) (daily wear only)

Multifocal Lens (Centered, Decentered, Crescent):

Diameter	8.8 to 11.0mm
Center Thickness	0.08 to 0.65mm (daily wear)
	0.08 to 0.38mm (extended wear)
Base Curve	7.00 to 9.00mm
Sphere Power	-13.00 to +5.00D
Add Power	+1.00 to +3.00D

The physical/optical properties of the lens are:

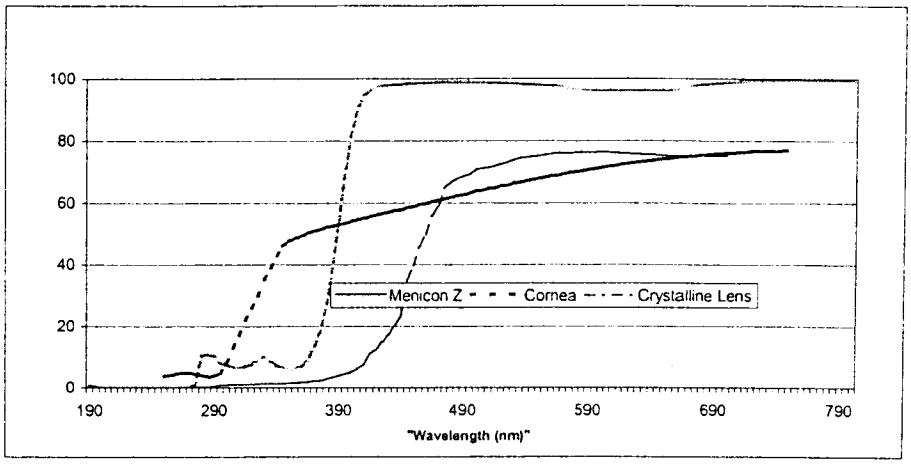
Specific Gravity:	1.20
Refractive Index:	n^{25}_D 1.436± 0.001
Surface Character:	Hydrophobic
Wetting Angle:	24 degrees (after soaking)
Light Transmittance:	Visible region >95% (380 nm – 780 nm)
	Ultraviolet region <6% (210 nm – 380 nm)
	(sample thickness 0.08mm)
Water Absorption:	Less than 0.5% by weight
Oxygen Permeability:	163×10^{-11} (cm^2/sec)(mL O_2/(mL x mmHg)) Dk*
	189×10^{-11}**
	250×10^{-11}***

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

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

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

WAVELENGTH nm



MENICON Z™ (tisilfocon A) Contact Lens - Spectral transmittance curve for Menicon Z™ (tisilfocon A) Contact Lens - D & C Green No. 6 and UV absorbing agent (sample thickness Menicon Z™ (tisilfocon A) lens polymer plate = 0.08mm, representing the thinnest marketed version of the lens).
CORNEA - Human cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, P. 58, figure 2-21.
CRYSTALLINE LENS - Human crystalline lens from a 25-year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

Note: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult the eyecare professional for more information.

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

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

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

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

Menicon Z™ (tisilfocon A) spherical, aspheric, non-prism ballast toric and non-prism ballast multifocal lenses are indicated for extended wear (from 1 to 30 days between removals for cleaning and disinfection of the lenses, as recommended by the eyecare professional) for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in non-aphakic persons with non-diseased eyes.

The lens may be prescribed in spherical and aspheric powers ranging from -25.00 D to +25.00 D for daily wear and -25.00 D to +8.00 D for up to 30 days extended wear. Toric lenses are designed to correct up to 5.00 D of astigmatism and multifocal lenses to provide up to +3.00 D of reading add power for up to 30 days extended wear.

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

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

CONTRAINDICATIONS (Reasons not to use)

DO NOT USE the Menicon Z™ (tisilfocon A) Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior segment of the eye
- Any eye disease, injury, or abnormality 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.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping.[1,2]
- 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. The long-term risk of microbial keratitis has not been determined for this lens when worn for greater than 7 days extended wear. Postmarketing studies are in progress to evaluate the risk up to 30 days.
- 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.

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

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

PRECAUTIONS:

CAUTION: NON-STERILE. ALWAYS CLEAN AND DISINFECT LENSES PRIOR TO USE.

Special Precautions for Eyecare Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens and wear schedule for a patient, the eye care professional should consider all lens characteristics that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

  Lens designs with an average thickness over the central 6 mm greater than 0.19 mm (Rx outside the range of –0.25 to –15.00 in thin lens designs) do not provide oxygen transmissibility above the established threshold level required to prevent overnight corneal edema[3]. Thin lens designs should always be considered when fitting patients for extended wear. Deswelling rates with RGP lenses have been shown to be rapid and nearly complete within the first three hours of awakening. The prescribing eye care professional should carefully assess the potential impact of these factors and carefully monitor the continuing ocular health of the patient and lens performance on the eye.
- 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.
- The following patients may not be suitable extended wear contact lens candidates, and/or may experience a higher rate of adverse effects associated with contact lens wear:
  - ◊ Patients with a history of acute inflammatory reactions to contact lens wear.
  - ◊ Patients with a history of giant papillary conjunctivitis associated with contact lens wear.
  - ◊ Patients with a history of ocular allergies may need to temporarily discontinue lens wear during certain times of the year.
  - ◊ Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule, or follow-up visit schedule.
  - ◊ Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.
  - ◊ Patients who are unwilling or unable to adhere to a recommended care regimen, or who are unable to insert and remove lenses, should not be provided with them.
- 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™ (tisilfocon A) Contact Lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)
- Some patients will not be able to tolerate continuous wear even if able to tolerate the same or another lens on a daily wear basis. Some patients who are able to tolerate continuous wear will not be able to wear their lenses continuously for 30 days. Patients should be carefully evaluated for continuous wear prior to prescription and dispensing, and eyecare professionals should conduct early and frequent follow-up examination to determine ocular response to continuous wear.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic and other post-surgical persons should not be fitted with Menicon Z™ (tisilfocon A) Contact Lenses until the determination is made that the eye has healed completely.
- Lenses are shipped in a plastic container immersed in Barnes-Hind® Comfort Care® GP Wetting & Soaking Solution. If the plastic container has missing solution or is dry, return the product to the Authorized Manufacturing Lab according to their 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.
- 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.

[3]Investigative Ophthalmology and Visual Science, October 1984; Vol 25, pp. 1161-1167

Eyecare professionals should carefully instruct patients about the following care regimen and safety precautions. It is strongly recommended that patients be provided with a copy of the Patient Instructions for the Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lens available from Menicon and understand its contents prior to dispensing the lenses.

Handling Precautions:

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

Solution Precautions:

- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may reduce the ability of the lens surface to return to a wettable state.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Do not heat the cleaning, wetting, and/or soaking solution and lenses. Keep away from extreme heat.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the Menicon Z™ (tisilfocon A) Contact Lenses.

Lens Wearing Precautions:

- Never wear lenses beyond the period recommended by the eyecare professional.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Non-Moving) Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eyecare professional.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions:

- Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with 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.

Topics to Discuss with the Patient:

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

Who Should Know That the Patient is Wearing Contact Lenses:

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

ADVERSE REACTIONS:
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
- Abnormal feeling that something is in the eye such as a foreign body or scratched area
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the 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.**

If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient **should immediately remove the lenses and contact his or her eyecare professional** or physician, who must determine the need for examination, treatment or referral without delay (See Important Treatment Information for Adverse Reactions). A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

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

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

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

Menicon Z™ (tisilfocon A) spherical or aspheric lenses and non-prism ballast toric and non-prism ballast multifocal lenses are indicated for extended wear (from 1 to 30 days between removals for cleaning and disinfection of the lenses, as recommended by the eyecare professional) for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in 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 the 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.

The patient characteristics necessary to achieve success with Menicon Z lenses are similar to those for other rigid gas permeable contact lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for rigid gas permeable contact lens wear. It is necessary to make an assessment of general health, patient hygiene, motivation and the willingness to comply with practitioner instructions.

While Menicon Z lenses are indicated for up to 30 days/29 nights of continuous wear, you patients should be told to follow some basic safety precautions. Patients should check their eyes every day to make sure they are comfortable and free of redness or irritation, and that their vision is clear. The Patient Instructions booklet contains a list of problem symptoms and patients should be instructed to contact you if a problem persists.

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 contact lens wear (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™ (tisilfocon A) Contact Lens material requires modification of the Burton lamp to visualize fluorescein patterns adequately. Burton lamp conversion kits are available upon request by calling the Authorized Manufacturing Lab.

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	• Thin design (0.15mm for –3.00, 0.10mm min.) • Diameter 8.0 to 11.0 • Designed for alignment fit with lid interaction • Lenticulation designed to provide uniform edge profiles • Moderate to high edge lift	• 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 • Extended Wear
Aspheric	• 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, 0.11mm min.) • Base curve available in 0.10mm increments • Designed for alignment fit, with diameters to provide under lid positioning • Low to moderate edge lift	• 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	• The original Menicon design • Diameters 8.8, 9.2 and 9.6mm • 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, 0.12mm min.)	• 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 9.2mm and 9.6mm 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	9.2mm Diameter	9.6mm Diameter
Spherical to 0.75D	on K_{flat}	0.25D (0.05mm) flatter than K_{flat}
1.00 to 1.75D	0.25D (0.05mm) steeper than K_{flat}	on K_{flat}
2.00 to 2.50D	0.50D (0.10mm) steeper than K_{flat}	0.25D (0.05mm) steeper than K_{flat}
over 2.50D	toric lens recommended	toric lens recommended

MENICON ALPHA 1 DESIGN

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

MENICON ASPHERIC DESIGN

Corneal Astigmatism	Base Curve Selection
0 to 0.75D	Fit on K_{flat} (round to next flatter BC)
1.00 to 1.75D	Fit on K_{flat} (round to next steeper BC)
2.00 to 2.50D	Fit 0.10mm steeper than K_{flat} (round to next steeper BC)
Greater than 2.50D	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 (**S**teeper **A**dd **M**inus **F**latter **A**dd **P**lus) 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 well 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 2.50D with-the-rule (WTR) or 1.50D 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

$K_H - K_V = 43.00 - 46.00 = -3.00D$ (WTR)

2) Is there a difference of more than 0.75D 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:

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 9.4mm). 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 3D total corneal astigmatism

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

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

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	-1.00DS	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**

Note: Prism Ballast Lens Designs are not approved for extended wear indications.

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 9.2mm 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.

Note: Prism Ballast Lens Designs are not approved for extended wear indications.

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 dioptric value of the back surface cylinder.

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

Note: Prism Ballast Lens Designs are not approved for extended wear indications.

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 $_{\text{corneal plane}}$: − 1.00 − 3.75 x 180

Flat meridian: 43.00/−1.00; on K fit, 9.2mm diameter → 7.85 mm (43.00D) / −1.00
Steep meridian: 46.00/−4.75; fit 1D flat, 9.2mm diameter → 7.50mm (45.00D) / −3.75

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

Note: Prism Ballast Lens Designs are not approved for extended wear indications.

3. MULTIFOCAL LENSES

All patients do not function equally well with multifocal 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 multifocal lenses, 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 multifocal contact lenses provide.

Menicon Decentered Target Design Lens Fitting Procedure (Daily Wear Only)
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	Viewing Demands
Aperture size normal to large	Heavy near and intermediate requirements
Lower lid at or above lower limbus in primary gaze	Near and/or intermediate demands in all gazes
Upper lid in upper 1/3 of cornea or higher	Add requirements minimal to high
Pupil size average to large	
Spherical or low to moderate with-the-rule corneas	

a. Diameter Selection
Menicon recommends beginning with a moderate diameter with truncation for the initial lens (9.4/9.0mm). 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 0.50D 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 4.0mm with a 4.5mm 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 0.1mm 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 0.3mm.*

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 Lens Design

- 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 (Daily Wear Only)

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:

Physical Features	Viewing Demands
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 of 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 (9.4/9.0mm). 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 0.50D 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 4.0mm. 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 0.1mm 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 0.3mm.*

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 (Appropriate for Daily and Extended Wear)

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	Viewing Demands
Ideal for small apertures	Heavy near and intermediate requirements
Works well with very large apertures or where lower lid is below lower limbus	Near and/or intermediate demands in all gazes
Pupil size average to large	Add requirements minimal to high
Spherical or with-the-rule corneas best	
Toric back and front surfaces available to accommodate most corrections	

a. Diameter Selection

Menicon recommends beginning with a moderate diameter for the initial lens (9.0 to 9.4mm). 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 0.50D 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 4.0mm. 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 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.
- 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

- Follow-up examinations, as recommended by the 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.
- 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.
- 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.
- After the lens removal, instill sodium fluorescein into the eyes and conduct a thorough biomicroscopy examination.

- The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.

- 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) Contact 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

The wearing schedule should be determined by the eyecare professional. Not all patients can achieve the maximum wear time of up to 30 days of continuous wear. Patients should be monitored closely during the first month of 30-day continuous wear. **If problems occur during this first month, the patient may not be suitable for the full 30-day wearing schedule.** The maximum suggested wearing time should be determined by the eyecare professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. Regular check-ups, as determined by the eyecare professional, are extremely important.

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.

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)*

Day	Hours
1	4-8
2	6-10
3	8-14
4	10-15
5	12-all waking hours
6 and after -	all waking hours

*If the lenses continue to be well tolerated.

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

Extended Wear (Overnight)

- **Lens Designs Approved for extended wear range from +8.00 to −25.00D. Prism ballast designs are not approved for extended wear.**
- **It is suggested that new contact lens wearers first be evaluated on a daily wear schedule. If the patient is judged to be an acceptable extended wear candidate, the eyecare professional may determine an extended wear schedule based upon the response of the patient.**
- The eyecare professional should establish an extended wear period up to a maximum of 30 continuous days/29 nights that is appropriate for each patient. Once the lenses are removed, the patient's eyes should have a rest period with no lens wear of overnight or longer, as recommended by the eyecare professional.
- See **WARNINGS** for information about the relationship between wearing schedule and corneal complications and **CLINICAL RESULTS** for important information about average wear times and other study findings.

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 with 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 is 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) Contact Lenses.

HANDLING OF MENICON Z™ (tisilfocon A) CONTACT LENSES

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 the patient is able to put on the lenses and remove them before the patient leaves your office.

PATIENT 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 (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.

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 eyecare professional
Disinfection/Storage	CLARIS® Cleaning and Soaking Solution
Lubrication/Rewetting	CLARIS® Rewetting Drops
Periodic Protein Cleaning	ProFree / GP Weekly Enyzmatic Cleaner

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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 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 that 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 (NON-MOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 10 minutes, the lens edge should be gently manipulated using the eyelid (do not touch the lens directly), and the patient should immediately consult the eyecare professional.

HOW SUPPLIED

Each Menicon™ (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 plastic container upon receipt, rinsed with fresh saline solution, cleaned with a cleaner and placed in another prescribed disinfecting solution prior to dispensing. Follow the manufacturer's instructions on the disinfecting solution label.

Dry shipped lenses are available upon request.

The plastic container 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) Contact Lenses, please call the authorized Manufacturing Lab.

REPORTING OF ADVERSE REACTIONS

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

Authorized Manufacturing Lab
Street Address
City, State Zip
Telephone Number