PROFESSIONAL FITTING AND INFORMATION GUIDE

(FOR DAILY WEAR CORNEAL AND SCLERAL CONTACT LENSES)

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

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

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INTRODUCTION

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

DESCRIPTION

The **Menicon Z™ (tisilfocon A)** Rigid Gas Permeable contact lens is available as a daily wear spherical, aspheric, toric or multifocal design.

Scleral contact lenses are available for daily wear only.

Contact lenses for the management of irregular corneas are available for daily wear only.

The lens material (tisilfocon A) is a thermoset copolymer derived from fluoro-methacrylate and siloxanylstyrene, bound by crosslinking agents. The contact lenses are available in a clear and a light blue tint. The light 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.

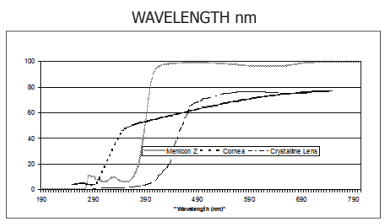
The **Menicon Z™ (tisilfocon A)** contact lens is a hemispherical shell of the following dimensions (not all parameter combinations are available in all designs):

Spherical and Aspheric Contact Lens	
Diameter	7.0 to 21.0 mm
Center Thickness	0.08 to 0.50 mm
Base Curve	4.00 to 11.5 mm
Powers	-25.00 to +25.00 D (in 0.25 D steps)
Toric Contact lens	
Diameter	7.0 to 21.0 mm
Center Thickness	0.08 to 0.50 mm
Base Curve	7.30 to 8.50 mm
Sphere Powers	-10.00 to +8.00 D (in 0.25 D steps)
Cylinder Powers	-0.50 to -5.00 D (in 0.25 D steps)
Prism Ballast	0.75 to 2.00 D (in 0.25 D steps)
Truncation Height	0.0 to 1.0 mm (in 0.1 mm steps)
Multifocal Contact Lens (Centered, Decentered, Crescent)	
Diameter	8.8 to 21.0 mm
Center Thickness	0.08 to 0.65 mm
Base Curve	7.00 to 9.00 mm
Sphere Power	-13.00 to +5.00 D
Add Power	+1.00 to +3.00 D

The physical/optical properties of the contact lenses are:

Specific Gravity: **1.20**
Refractive Index: **n_D^{25} 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 0.08 mm)
Water Absorption: **Less than 0.5% by weight**
Oxygen Permeability: **$163x10^{-11}$ (cm^2/sec)(mL 0_2/(mL x mmHg)) Dk***
$189x10^{-11}$**
$250x10^{-11}$***

* Method for determination of oxygen permeability: ISO 18369-4 2017. Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials
** Measurement of Dk by Fatt, Polarographic method. (PHEMA Standard)
*** Measurement of Dk by the Hamano Polarographic method. (Teflon Standard)



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

Cornea:
- Human cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, P. 58, figure 2-21.

Crystalline Lens:
- Human crystalline lens from a 25-year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

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

PRODUCT NAME LIST

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

Product Name	Abbreviation
SynergEyes GP	SynergEyes GP
SynergEyes GP Front toric	SynergEyes GP FtrTor
SynergEyes GP Bitoric	SynergEyes GP Bitor
SynergEyes GP Bitoric Extra	SynergEyes GP Bitor Ext
SynergEyes GP Progressive D	SynergEyes GP Pro D
SynergEyes GP Progressive N	SynergEyes GP Pro N
SynergEyes GP Progressive D Plus	SynergEyes GP Pro D+
SynergEyes GP EP	SynergEyes GP EP
SynergEyes GP Bitoric Extra Progressive	SynergEyes GP Bitor Ext D
SynergEyes GP Bitoric Progressive	SynergEyes GP Bitor Pro D
SynergEyes GP Bitoric Progressive Plus	SynergEyes GP Bitor Pro D+
SynergEyes GP Bitoric Extra Progressive Plus	SynergEyes GP Bitor Ext Pro D+
SynergEyes GP II	SynergEyes GP II
SynergEyes GP II Bitoric	SynergEyes GP II Bitor
SynergEyes GP II Bitoric Extra	SynergEyes GP II Bitor Ext
SynergEyes GP II EP	SynergEyes GP II EP
SynergEyes GP II Progressive D	SynergEyes GP II Pro D
SynergEyes GP II Progressive N	SynergEyes GP II Pro N
SynergEyes GP II Bitoric Progressive	SynergEyes GP II Bitor Pro D
SynergEyes GP II Bitoric EP	SynergEyes GP II Bitor EP
SynergEyes GP II Bitoric Extra Progressive	SynergEyes GP II Bitor Ext Pro D
SynergEyes GP II Bitoric Extra EP	SynergEyes GP II Bitor Ext EP
SynergEyes GP II Progressive D Plus	SynergEyes GP II Pro D+
SynergEyes VS - Sphere	SynergEyes VS Sph
SynergEyes VS	SynergEyes VS
SynergEyes VS XL - Sphere	SynergEyes VS XL Sph
SynergEyes VS XL	SynergEyes VS XL
SynergEyes VS XL QT	SynergEyes VS XL QT

ACTIONS

The **Menicon Z™ (tisilfocon A)** contact lens, when put on the cornea, acts as a refracting medium to focus light rays on the retina. The **Menicon Z™ (tisilfocon A) Scleral** contact lens, when put on the conjunctiva, vaults over the cornea and acts as a refracting medium to focus light rays on the retina.

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

The **Menicon Z™ (tisilfocon A)** Rigid Gas Permeable contact lens is available as a spherical, aspheric, toric or multifocal design and is intended for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic disease-free eyes.

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

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

CONTRAINDICATIONS

DO NOT USE the **Menicon Z™ (tisilfocon A)** contact lens when any of the following conditions exist:
- Acute and subacute inflammation or infection of the anterior segment of the eye
- Any eye disease, injury, or abnormality (other than irregular corneal conditions as described in 'INDICATIONS') that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes), except when using the scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and contact lens
- Corneal hypoesthesia (reduced corneal sensitivity), except when using the scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and contact lens and acts as a protective barrier for the cornea
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues that may be induced or exaggerated by wearing contact lenses and/or using contact lens solutions
- Allergy to any ingredient, such as mercury or thimerosal, in the solution which is to be used for the care of the **Menicon Z™ (tisilfocon A)** contact lens
- Any active corneal infection
- If eyes become red or irritated.
- Incomplete corneal healing following eye surgery

WARNINGS

Patients should be advised of the following warnings pertaining to wearing contact lenses:
- Problems with contact lenses and lens care products could result in **serious injury** to the eyes. It is essential that patients follow the directions of the eye care professional or practitioner and all instructions on the labels for proper use of contact lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear contact lenses (such as lenses for irregular corneas, including keratoconus) are not intended for overnight wear, and patients should be instructed not to wear contact lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions increases when daily wear contact lenses are worn overnight.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when contact lenses are worn overnight or while sleeping.[1,2]
- If a patient experiences **eye discomfort**, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove the contact lenses** and promptly consult the eye care professional or practitioner.
- **UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. The contact lens users should continue to use their protective UV-absorbing eyewear as directed.**
- Never use tap water for the care of the contact lenses and lens cases.
- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If contact lenses have been submersed in water such as when swimming in pools, lakes or oceans, the user should thoroughly clean and disinfect the contact lenses before wearing them again. Ask the eye care professional or practitioner for recommendations about wearing contact lenses during any activity involving water.

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

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

Special Precautions for Eye Care Professional or Practitioner:
- Due to the small number of patients enrolled in clinical investigation of contact lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting appropriate contact lenses and wearing schedule for a patient, the eye care professional or practitioner should consider all lens characteristics that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eyes should be carefully monitored by the prescribing eye care professional or practitioner.
- The following patients may experience a higher rate of adverse reactions associated with wearing contact lenses:
  - ◇ Patients with a history of acute inflammatory reactions to wearing contact lenses.
  - ◇ Patients with a history of giant papillary conjunctivitis associated with wearing contact lenses.
  - ◇ Patients with a history of ocular allergies that may need to temporarily discontinue wearing contact lenses 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 unable or unwilling to adhere to a recommended care regimen, or who are unable to put in and remove contact lenses, should not be provided with the contact lenses.
- Eye care professional or practitioner should instruct patients to remove contact lenses immediately if the eyes become red or irritated.
- The use of fluorescein is contraindicated in those people who have a known hypersensitivity to any component.
- The presence of the UV absorber in the **Menicon Z™ (tisilfocon A)** contact lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the following descriptions in this document for detailed instructions.)
- Follow-up visits are necessary to assure the continuing health of patient's eyes. Patients should be instructed as to a recommended follow-up schedule.
- Aphakic and other post-surgical patients should not wear the **Menicon Z™ (tisilfocon A)** contact lens until the determination is made that the eye has healed completely.
- The contact lenses are shipped immersed in Menicon Unique pH® Multi-Purpose Solution in foil-sealed individual plastic containers. If the foil-sealed plastic container has missing solution or is dry, return the product to the supplier according to their return policies.
- If a patient is sensitive to any ingredient in the shipping solution, the contact lenses should be removed from the foil-sealed plastic containers upon receipt, rinsed with fresh saline solution, cleaned with a cleaner and put in another prescribed disinfecting solution prior to dispensing the contact lenses. Follow the manufacturer's instructions on the disinfecting solution label.
- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best-corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- It is advised that wound healing and corneal curvature are stable prior to putting in the **Menicon Z™ (tisilfocon A)** contact lens for post-surgical or other compromised corneas.

The eye care professional or practitioner 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 the contents prior to dispensing the contact lenses.

Handling Precautions:
- Always wash and rinse hands before handling contact lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the contact lenses. It is best to put in contact lenses before putting on makeup. Water-based cosmetics are less likely to damage contact lenses than oil-based products.
- Before leaving the office of the eye care professional or practitioner, the patient should be able to promptly remove contact lenses or should have someone else available who can remove the contact lenses for the patient.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the contact lenses may occur, causing distorted vision and/or injury to the eyes.
- Always handle contact lenses gently and avoid dropping them on hard surfaces.
- Do not touch contact lenses with fingernails.
- Carefully follow the handling, putting-in, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the **Menicon Z™ (tisilfocon A)** contact lens and those prescribed by the eye care professional or practitioner.
- Never use tweezers or other tools to remove the contact lenses from the plastic container or lens case unless specifically indicated 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 non-preserved solutions, when used, should be discarded after the time specified in the directions on the label.
- Always keep the contact lenses completely immersed in the recommended storage solution when the contact lenses are not in use. Prolonged periods of drying may reduce the ability of the lens surface to return to a wettable state.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting contact lenses.
- Different solutions cannot always be used together, and not all solutions are safe for use with all contact lenses. Use only recommended solutions.
- Do not heat the cleaning, wetting, and/or soaking solution and contact lenses. Keep them away from extreme heat.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the contact lenses.

Lens Wearing Precautions:
- Never wear contact lenses beyond the period recommended by the eye care professional or practitioner.
- If the contact lenses stick (stop moving) on the eyes, follow the recommended directions in 'CARE FOR A STICKING (NON-MOVING) LENS'. The contact lenses should move freely on the eyes for the continued health of the eyes. If non-movement of the contact lenses continue, the patient should be instructed to immediately consult the eye care professional or practitioner.
- Avoid all harmful or irritating vapors and fumes while wearing contact lenses.
- If aerosol products such as hair spray are used while wearing contact lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions:
- Lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with the sterile contact lens solution recommended by the lens case manufacturer (never use tap water), and allowed to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens manufacturer or the eye care professional or practitioner.

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

ADVERSE REACTIONS

- Eye stinging, burning, itching, or any other pain in the eyes
- Less comfort than when the contact lenses were first put in the eyes
- Continuous foreign body or scratching sensation

- Excessive tearing, unusual eye secretions, redness, reduced visual acuity, blurred vision, rainbows, halos, photophobia, or dry eyes

If any of the above problems occur, the patient should be instructed to:
- **Immediately remove the contact lenses.**
- If the discomfort or problem stops, look closely at the contact lenses. If the contact lenses are in any way damaged, do not put them back in the eyes. Put the contact lenses in a lens case and consult the eye care professional or practitioner. If the contact lenses have dirt, an eyelash, or other foreign body on them, or the problem stops and the contact lenses appear undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses, then put them in again. If the problem continues after putting in the contact lenses, the patient should **immediately remove the contact lenses and consult the eye care professional or practitioner.**

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

During use for the management of irregular corneal conditions, an adverse reaction may be due to the original condition or effects of wearing contact lenses. There is a possibility that the existing condition might become worse when a contact lens is used on an eye with an irregular corneal condition. The patient should be instructed to avoid serious eye damage by consulting the eye care professional or practitioner IMMEDIATELY if there is an increase in symptoms while wearing the contact lenses.

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

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. To prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical, 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 should be retained for analysis and culturing.

SELECTION OF PATIENTS
The **Menicon Z™ (tisilfocon A)** Rigid Gas Permeable contact lens is available as a spherical, aspheric, toric or multifocal design and is intended for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic disease-free eyes.

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

Patients who are unable or unwilling to adhere to a recommended care regimen for the **Menicon Z™ (tisilfocon A)** contact lens, or who are unable to put in and remove contact lenses, should not be provided with the contact lenses. 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 the **Menicon Z™ (tisilfocon A)** contact lens 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 wearing rigid gas permeable contact lenses. It is necessary to make an assessment of general health, patient hygiene, motivation and the willingness to comply with instructions of the eye care professional or practitioner.

PREPARATION FOR FITTING THE CONTACT LENSES
The **Menicon Z™ (tisilfocon A)** contact lens should be thoroughly cleaned with the recommended cleaning solution and disinfected/hydrated in the desired soaking/conditioning solution according to the directions on the label prior to putting in the contact lenses 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 wearing the contact lenses (consider patient hygiene, and mental and physical state).
- Make ocular measurements for initial contact lens parameter selection.
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

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

The following evaluations apply to all corneal lens designs:
a. Characteristics of a Well-Fitting Contact Lens
A well-fitting contact lens positions appropriately following the blink with minimal lag and the optical portion of the contact lens does not deviate from the pupil when the contact lens is drawn upwards. Ideally, the contact lens will ride up with the blink and then quickly return to a position of rest.
b. Characteristics of a Steep-Fitting Contact Lens
A steep-fitting contact lens usually shows restricted movement. The fluorescein pattern will show central pooling, excessive intermediate bearing with inadequate edge lift.
c. Characteristics of a Flat-Fitting Contact Lens
A flat-fitting contact lens will often position high under the upper lid or drop rapidly when released from the lid. The contact 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 contact lens is centered on the eye. Horizontal decentration or movement may also indicate a flat-fitting contact lens.
d. Fluorescein Evaluation
The fluorescein pattern should indicate good tear exchange with an alignment lens-to-cornea relationship. The presence of the UV-absorber in the **Menicon Z™ (tisilfocon A)** contact lens material requires modification of the Burton lamp to visualize fluorescein patterns adequately.

The following evaluations apply to all scleral lens designs:
a. Characteristics of a Well-Fitting Contact Lens
A well-fitting contact lens positions centered over the cornea or may lag slightly inferiorly. There is little or no movement of the contact lens with the blink. The contact lens completely vaults the cornea and the limbus. The fitting zone of the contact lens settles into the conjunctiva and aligns to the sclera.
b. Characteristics of a Tight-Fitting Contact Lens
A tight-fitting contact lens usually shows blanching of the bulbar conjunctival blood vessels as they pass under the fitting zone of the contact lens. There may be impingement of the larger blood vessels resulting in localized conjunctival congestion and inflammation. There may be no fluorescein/tear flow under the contact lens.
c. Characteristics of a Flat-Fitting Contact Lens
A flat-fitting contact lens will have an area of corneal touch or bearing. This will usually result in localized epithelial staining in the area of lens bearing. The contact lens may initially be comfortable for the patient, but wearing time is usually reduced due to increased discomfort with wearing the contact lens. The fluorescein pattern will show bearing or touch at the apex of the cornea, or where the elevation of the cornea is highest. Edge lift off may also indicate a flat-fitting contact lens.
d. Fluorescein Evaluation
The fluorescein tear flow test will demonstrate tear flow behind a scleral contact lens. Apply fluorescein to the front surface of a contact lens that has settled for the appropriate time (usually 20 to 30 minutes or longer). Fluorescein can be seen as it percolates behind the contact lens and colors the fluid in the chamber between the contact lens and cornea. This is best seen and evaluated using an optic section and white light at high intensity.

The fluorescein pattern can also be evaluated by adding fluorescein to the fluid in the cup of the contact lens prior to putting the contact lens in the eye. Instruct the patient to position the head parallel to the floor and to look directly down.
Fill the cup of the contact lens with non-preserved saline. Dip a fluorescein strip into the saline, adding fluorescein to the solution. Put the contact lens in the eye and allow it to settle for several minutes. Evaluate the fluorescein pattern using cobalt blue light and a yellow Wratten filter. Allow the contact lens to settle on the eye for 20 to 30 minutes or longer and evaluate the fluorescein pattern again.
This lens evaluation method will demonstrate areas of bearing, alignment and clearance. To estimate the amount of contact lens clearance, the eye care professional or practitioner must use an optic section and white light. Estimation of the fluid layer thickness can be made by referencing the thickness of the fluorescein colored green fluid in the optic section to the known thickness of the contact lens also seen in the optic section.
The presence of the UV-absorber in the **Menicon Z™ (tisilfocon A)** contact lens material requires modification of the Burton lamp to visualize fluorescein patterns adequately.
e. Bubble Evaluation
Immediately after putting in the contact lens, inspect the fit for bubbles trapped under the contact lens. If bubbles are present, remove the contact lens and then put it in. A properly placed contact lens will not have bubbles present in the fluid layer after putting in.

FITTING PROCEDURE
General Prescribing and Fitting Guidelines:
Menicon provides the eye care professional or practitioner with a choice of designs to accommodate almost any physical and optical requirements. Spherical and aspheric designs are sufficient for the majority of single vision and monovision prescribing needs, and toric and multifocal contact lenses are available for patients with more specialized fitting and/or optical needs.

The use of **Menicon Z™ (tisilfocon A)** contact lens on irregular corneas may require ordering contact lenses outside of the standard parameters used for healthy eyes. The modifications of base curve to peripheral lens curve relationships, reverse geometry curves to control the sagittal height of the contact lens, lens diameters and thickness profiles will frequently be necessary to optimize the fitting relationship for each individual eye. Standard measuring and testing equipment and ordering by keratometry and refractive measurements are generally inadequate in designing contact lenses for these conditions. Whenever possible, it is recommended that trial lenses designed for keratoconus, pellucid marginal degeneration, penetrating keratoplasty or refractive (e.g., LASIK) surgery be used by the eye care professional or practitioner to evaluate fitting relationships and to be able to better predict the success of such lens designs. In most cases, multiple contact lens orders and parameter adjustments will be necessary to achieve optimum fit. Corneal topography may be required to gain insight into the peripheral corneal geometry. If topography reveals an oblate corneal surface (steeper in the periphery relative to the central cornea, commonly seen after LASIK or penetrating keratoplasty), a reverse geometry contact lens will often be required. If the topography reveals high regular astigmatism, a bitoric lens design will often be required. If topography reveals a very defined and localized area of steepening and ectasia as in keratoconus, a keratoconus design which may include a decentered optic zone may be indicated. Large diameter contact lenses may also be indicated in highly irregular corneas where lens stability is difficult to achieve with smaller corneal lens designs.

The general requirements and recommendations for fitting each type of contact lenses are described below.

Refer to 'SCLERAL CONTACT LENS FITTING GUIDELINES' for additional information regarding the fitting of the scleral lens designs.

SPHERICAL AND ASPHERIC DESIGNS
a. Design Selection:
The table below lists the various spherical and aspheric designs available from Menicon, and recommendations for use.

Design	Description	Recommended Use
Aspheric	• Back surface low eccentricity aspheric design with junctionless periphery • Thin design • 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, and order • Available for inventory fitting
Spherical	• Designed for interpalpebral or under lid alignment philosophy • Lenticulars standard to provide uniform edge profile across powers • Low to moderate edge lift • Standard thickness	• Current 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. Diameter Selection:
Contact lens centration and the interpalpebral distance are important factors in selecting a lens diameter. A diameter between 9.2 mm and 9.6 mm is recommended for contact lenses where a diameter choice is required. Ideally, the upper edge of the contact 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 contact lens covers the pupil adequately in dim light.

c. Base Curve Selection:
Spherical Design:

Corneal Astigmatism	9.2 mm Diameter	9.6 mm Diameter
0 to 0.75 D	On K - 0.25 D FTKflat	0.25 D - 0.50 D FTKflat
>1.00 to 1.75 D	0.25 D STKflat - On K	On Kflat - 0.25 D FTKflat
>2.00 to 2.50 D	0.50 D - 0.25 D STKflat	0.25 D STKflat - On Kflat
> 2.50 D	Recommend toric	Recommend toric

Aspheric Design:

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

d. Power Selection:
1) Convert Rx to minus cylinder if necessary.
2) Correct for vertex distance if either meridian is greater than +/-4.00 using vertex distance chart.
3) Power will be equal to spherical component of the spectacle correction (corrected for vertex distance expressed in minus cylinder format) for an "On-K" fit.
4) SAMFAP (Steeper Add Minus Flatter Add Plus) correction must be made if the contact 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-Fitting Spherical/Aspheric Contact Lens:
- The contact lens should center well over the pupillary zone on the cornea.
- The contact lens should move freely with the blink.
- The fluorescein pattern should show good tear exchange.

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. Contact lenses can be designed with toric shapes and toric optics, toric shapes and spherical optics, or spherical back surfaces and toric optics. To determine whether a toric contact lens is needed, the eye care professional or practitioner should answer the following two questions.
1) Is there more than 2.50 D with-the-rule (WTR) or 1.50 D against-the-rule (ATR) corneal astigmatism (as measured by keratometry or topography)?

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

Calculation method:
- Subtract K reading closest to vertical or 90 degrees (KV) from K reading closest horizontal or 180 degrees (KH) using the dioptric values to get the corneal astigmatism value and orientation.
  ◇ Negative values indicate WTR astigmatism
  ◇ Positive values indicate ATR astigmatism

  Example:
  K's: 43.00@180/46.00@90
  K_H - K_V = 43.00 - 46.00 = -3.00 D (WTR)

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

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

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

  Example:
  K's: 43.00@180/46.00@90; RxSpec: –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 describes 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} - $Cyl_K > 0.75$ D
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} - $Cyl_K > 0.75$ D

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

b. Base Curve Selection:
The base curve for a front toric design should be selected according to the rules for a spherical contact lens.

For toric base curves (back torics and bitorics), the flat curve should be selected according to the rules for a spherical contact 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
KH - KV = 43.00 - 46.00 = -3.00 (WTR) or 3D total corneal astigmatism
Flat BC = on flat K = 43.00 D (7.85 mm)
Steep BC = 3 – 1 or 2 diopters steeper = 45.00 D (7.50 mm)

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

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

Back toric:
The use of a back toric only contact 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 contact lens is indicated.

Example:
K's: 45.00/43.00@90 (pl - 2.00 x 90)
RX: +2.00 - 3.00 x 90
Refractive/Corneal cyl ratio = 3/2 = 1.5 (back toric indicated)
Select base curves equal to corneal cylinder for ATR cornea:
43.00/45.00 for 9.2 mm lens

Calculate the spherical power as for a spherical contact lens; the additional toric power needed will be created by the back surface.

Note:
- This contact lens will have a cylindrical power when read in a lensometer.

SPE Bitoric:
An SPE bitoric corrects only corneal astigmatism, just as a spherical contact lens does. The powers on an SPE are just as simple to calculate. The first power is calculated exactly as for a spherical contact 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 contact 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 corneal plane: – 1.00 – 2.75 x 180
BC selection (2D toricity, on K): 7.85/7.50 mm (43.00/45.00 D)
Power: –1.00/–3.00 (on K/2D more minus)

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

Example:
K's: 43.00@180/46.00@90; Rx corneal plane: – 1.00 – 3.75 x 180
Flat meridian: 43.00/–1.00; on K fit, 9.2 mm diameter ➔ 7.85 mm (43.00 D) / –1.00
Steep meridian: 46.00/–4.75; fit 1D flat, 9.2 mm diameter ➔ 7.50 mm (45.00 D) / –3.75
Final lens order: 7.85/7.50 (43.00 D/45.00 D); 9.2 mm diameter; –1.00/–3.75

MULTIFOCAL DESIGN
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 contact 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 gazes that multifocal contact lenses provide.

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

The Menicon Decentered Target Design is excellent for patients who would do well in a spectacle lens with a progressive style of near add, and 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 (9.0 to 9.4 mm). Contact lenses which are too large in the vertical diameter may interact excessively with the upper lid causing a contact 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 contact lens should rest on the lower lid or at the lower limbus, with the upper edge of the contact lens resting at or just under the upper lid margin. Generally, problems with contact lens translation should be addressed by altering the vertical (truncated) dimension of the contact lens. If the lower lid is too low to allow positioning of the optical zone over the pupil without excessive upper lid interaction, a centered target design should be used.

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

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

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

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

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

e. Characteristics of a Well-Fitting Menicon Decentered Target Lens Design:
- The contact lens rests on the lower lid margin or at the inferior limbus with the upper edge near the upper lid margin.
- The contact lens moves up minimally with the blink and quickly returns to its resting position at the lower lid.
- The contact lens should translate up freely on down gaze, with the truncation remaining on the lower lid during translation.
- The distance-to-near transition zone should be intermediate between the patient's habitual reading position and primary gaze.

Menicon Crescent Seg Design Lens Fitting Procedure:
The Menicon Crescent Seg Design is a one-piece, front surface add bifocal which works on the alternating or translating vision principle. It offers a large distance viewing zone as well as a large near area for maximum visual performance in all gazes.

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

Physical Features	Viewing Demands
Aperture size normal to large	Mainly distance and 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 (9.0 to 9.4 mm). Contact lenses which are too large in the vertical diameter may interact excessively with the upper lid causing a contact 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 contact lens should rest on the lower lid or at the lower limbus, with the upper edge of the contact lens resting at or just under the upper lid margin. Generally, problems with contact lens translation should be addressed by altering the vertical (truncated) dimension of the contact lens. If the lower lid is too low to allow positioning of the optical zone over the pupil without excessive upper lid interaction, a centered target design should be used.

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

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

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

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

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

e. Characteristics of a Well-Fitting Menicon Crescent Seg Design Lens:
- The contact lens rests on the lower lid margin or at the inferior limbus with the upper edge near the upper lid margin.
- The contact lens moves up minimally with the blink and quickly returns to its resting position at the lower lid.
- The contact lens should translate up freely on down gaze, with the truncation remaining on the lower lid during translation.
- The distance-to-near transition zone should be intermediate between the patient's habitual reading position and primary gaze.

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

Physical Features	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 (9.0 to 9.4 mm). The horizontal diameter should provide coverage of approximately 75 to 80% of the horizontal visible iris diameter.

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

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

d. Distance Zone Size Selection:
Menicon recommends an initial distance zone size of 3.5 to 4.0 mm. When viewed with fluorescein, the distance zone should be visible as a bright green round pool centered over the pupil in primary gaze. Near vision performance should be evaluated with the best distance over-refraction in place in trial lenses (do not use a phoropter for near testing). The patient should place normal reading material at their normal reading 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-Fitting Menicon Centered Target Design Lens:
- The contact lens is well centered throughout the blink cycle.
- The contact lens moves up minimally with the blink and quickly returns to a centered position.
- The contact 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 distance-to-near transition zone should be intermediate between the patient's habitual reading position and primary gaze.

FOLLOW-UP CARE FOR ALL CONTACT LENSES
- Follow-up examinations, as recommended by the eye care professional or practitioner, are necessary to ensure continued successful contact lens wearing. 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 wearing contact lenses.
- With contact lenses in place on the eyes, evaluate fitting performance to assure that characteristics of a well-fitting contact lens continue to be satisfied for the appropriate lens design. Examine the contact lenses closely for surface deposition and/or damage.
- After removing the contact lens, 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 contact lens, a reaction to solution preservatives, excessive contact lens wear, and/or a poorly fitting contact lens.
- Papillary conjunctival changes may be indicative of an unclean and/or damaged contact lens.

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

IN-OFFICE CARE OF TRIAL LENSES
The eye care professional or practitioner 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 foil-sealed plastic container. Hands should be thoroughly washed, rinsed, and dried with a lint free towel prior to handling contact lenses.

NON-STERILE, CLEAN AND CONDITION CONTACT LENSES PRIOR TO USE.

WEARING SCHEDULE

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

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

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

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

Although many eye care professionals or practitioners 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 eye care professional or practitioner regardless of how comfortable the contact lenses feel.

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

During Waking Hours*

DAY	1	2	3	4	5	6 and after
HOURS	4-8	6-10	8-14	10-15	12-all waking hours	All waking hours

* If the contact lenses continue to be well tolerated.

The contact lenses should be removed at the end of each day for cleaning and disinfecting (according to lens care system instructions).

CLINICAL ASSESSMENT
- Vision should be crisp and clear after the blink.
- The eye should be white and quiet.

Temporary discomfort may be caused by a foreign body under the contact lens surface. The contact lens should be removed, rinsed and put in again. If the discomfort persists, the patient should consult the eye care professional or practitioner before returning to wearing the contact lens.

MONOVISION CONTACT LENS FITTING GUIDELINES
a. Patient Selection:
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 correction 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. Wearing monovision contact lenses may not be optimal for such activities as:
- Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities
- Driving automobiles (e.g., driving at night). Patients who cannot pass their state driver's license requirements with monovision correction should be advised not to drive with the contact lens, OR may require that additional overcorrection be prescribed.

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 correction, 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 gazes that monovision contact lenses provide.

b. Eye Selection:
Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.
- 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.
- 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.
- 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 contact lens on the left eye.

c. 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 contact 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 contact 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 eye uncorrected for near.

d. Near Add Determination:
Always prescribe the less 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.

e. Trial Lens fitting:
Perform a trial lens fitting in the office to allow the patient to experience monovision correction. Fit contact lenses according to the directions in the general fitting guidelines and base curve selection described earlier in this document.

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 correction.

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

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

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

f. Adaptation
Visually demanding situations should be avoided during the initial wearing period. Some patients may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. The eye care professional or practitioner should explain the adaptational symptoms to the patients. 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 contact 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 period. This is particularly true when driving at night. Before driving an automobile, 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 wearing the contact lenses, 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.

g. Other suggestions
The success of the monovision correction may be further improved by having the patients 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 glasses 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 monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision correction 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 gazes with monovision.

The decision to fit a patient with monovision correction is most appropriately left to the eye care professional or practitioner 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 the **Menicon Z™ (tisilfocon A)** contact lens.

SCLERAL CONTACT LENS FITTING GUIDELINES
Pre-Fitting Examination:
The flatter keratometry reading (Kflat) and amount of corneal astigmatism should be determined. If corneal topography is done, note the steepest area on the map and the temporal quadrant. Using the Elevation map, determine the highest point on the cornea. Measure the corneal limbal size. If accurate corneal measurements are not possible, choose a steep contact lens.

Looking from the side, estimate the sagittal height of the cornea and adjacent sclera.

a. Lens Diameter Selection:
Select the appropriate lens diameter based on the condition of the eye and available parameters. Select a lens diameter that will be able to vault the cornea and limbus and have an adequate diameter fitting zone beyond the limbus (probably 1 to 2 mm). Large HVID cornea may require an 18 mm diameter contact lens whereas normal and small HVID cornea probably will be well fit with a 16 mm diameter contact lens.

b. Base Curve Selection:
Contact lenses designed to vault the cornea and limbus are most easily fit using the sagittal height of the cornea and the sagittal depth of the contact lens. Achieving clearance over the cornea and limbus is most easily determined using a trial lens set based on contact lenses with increasing amounts of sagittal depth.

A properly fit base curve will vault over the cornea avoiding all corneal touch. There should be no bubbles under the contact lens. Bubbles captured under the contact lens are most probably due to air capture when putting a contact lens in the eye. Remove the contact lens and put it in again.

c. Lens Power Selection:
Lens power can best be determined by adding the spherical value of the over-refraction to the trial lens power.

d. Fluorescein Examination:
The fluorescein examination can best be conducted by adding fluorescein to the cup of the contact lens prior to putting the contact lens in the eye. Evaluation of a trial lens that has apical touch is the best way to determine the proper sag. If central bearing is noted, the sag value should be increased by 0.1 mm for every 1.0 mm of touch. The optimal fit will be obtained with the minimum sag value that vaults the cornea with no apical bearing. The ideal pattern aligns the cornea with no bubbles at the limbus or under the optical cap.

The following evaluations apply to all scleral lens designs:
a. Characteristics of a Well-Fitting Contact Lens
A well-fitting contact lens positions centered over the cornea or may lag slightly inferiorly. There is little or no movement of the contact lens with the blink. The contact lens completely vaults the cornea and the limbus. The fitting zone of the contact lens settles into the conjunctiva and aligns to the sclera. Bubbles should not be observed under the contact lens at any location (very small bubbles less than 0.10 mm can be ignored). There should not be any conjunctival impingement or excessive edge lift.
b. Characteristics of a Tight-Fitting Contact Lens
A tight-fitting contact lens usually shows blanching of the bulbar conjunctival blood vessels as they pass under the fitting zone of the contact lens. There may be impingement of the larger blood vessels resulting in localized conjunctival congestion and inflammation. There may be no fluorescein/tear flow under the contact lens.
c. Characteristics of a Flat-Fitting Contact Lens
A flat-fitting contact lens may initially be comfortable for the patient, but wearing time is usually reduced due to increased discomfort with wearing the contact lens. The fluorescein pattern will show bearing or touch at the apex of the cornea, or where the elevation of the cornea is highest. Edge lift off may also indicates a flat-fitting contact lens. A flat-fitting contact lens may result in localized epithelial staining in the area of contact lens bearing.
d. Fluorescein Evaluation
The fluorescein pattern can be evaluated by adding fluorescein to the fluid in the cup of the contact lens prior to putting the contact lens in the eye. Instruct the patient to position the head parallel to the floor and to look directly down. Fill the cup of the contact lens with non-preserved saline. Dip a fluorescein strip into the saline, adding fluorescein to the solution. Put the contact lens in the eye and allow it to settle for several minutes. Evaluate the fluorescein pattern using cobalt blue light and a yellow Wratten filter. Allow the contact lens to settle on the eye for 20 to 30 minutes or longer and evaluate the fluorescein pattern again.
This lens evaluation method will demonstrate areas of bearing, alignment and clearance. To estimate the amount of contact lens clearance, the eye care professional or practitioner must use an optic section and white light. Estimation of the fluid layer thickness can be made by referencing the thickness of the fluorescein colored green fluid in the optic section to the known thickness of the contact lens also seen in the optic section.
The presence of the UV-absorber in the **Menicon Z™ (tisilfocon A)** contact lens material requires modification of the Burton lamp to visualize fluorescein patterns adequately.
The fluorescein tear flow test will demonstrate tear flow behind a scleral contact lens. Fluorescein is applied to the front surface of a contact lens that has settled for the appropriate time (usually 20 to 30 minutes or longer). Fluorescein can be seen as it percolates behind the contact lens and colors the fluid in the chamber between the contact lens and cornea. This is best seen and evaluated using an optic section and white light at high intensity.
e. Bubble Evaluation
Immediately after putting in the contact lens, inspect the fit for bubbles trapped under the contact lens. If bubbles are present, remove the contact lens and then put it in. A properly placed contact lens will not have bubbles present in the fluid layer after putting in.

The periphery should be evaluated once the ideal corneal clearance has been achieved. The edge should be adjusted if there is excessive edge lift or conjunctival impingement.

Troubleshooting:
- Corneal edema:
This can be caused by excessive corneal vaulting, poor tear flow or increased lens thickness or a combination of all these factors. The sag value should be re-evaluated to obtain the minimum sag that vaults with no apical bearing. Peripheral conjunctival impingement may be another possible cause for edema. The Peripheral curves (PCs) should be flattened with maintenance of the appropriate sag.
- Lens Awareness:
This can be caused by excessive edge lift, due to the PCs being too flat or the sag being too low. The first step would be to determine whether the sag is appropriate. In many cases, the edge will improve when the sag is increased. If the sag is correct, steepening or flattening of the periphery may correct the problem.
- SPK:
This may be caused by any apical bearing or a sensitivity to the solution used to fill the lens cup.
- Decreased visual acuity:
If patients complain of decreased visual acuity after 8 to 10 hours of wearing contact lenses, have the patient clean, disinfect and reinsert the contact lens after a few hours of wearing.
- Excessive redness:
This may be a sign that the contact lens is fitting too tight, the patient is using preserved solutions to put the contact lens in the eye, or there is meridional tightness of the contact lens fit.

Patient Instructions:
Patients should be instructed in the procedures for putting in and removing the contact lenses. Patients may find it easiest to use the tripod insertion method. Place the contact lens between the thumb, index and middle fingers for putting in the contact lens. The patient should be instructed to completely fill the cup of the contact lens with the recommended non-preserved solution, avoiding any bubbles. While facing downward toward a table top, the completely filled contact lens should be put in the eye as the patient looks directly at the center of the contact lens using the other hand and a free finger of the hand placed with the contact lens to retract the eyelids away from the eye. Immerse the cornea into the cup of fluid, gently put the contact lens on the cornea. Do not press the contact lens onto the cornea, this will create negative pressure under the contact lens creating a tight fitting contact lens. Gently release eye lids. Check for bubbles. The contact lens should feel comfortable and the vision should clear as the excessive fluid is expelled from the eye.

Patients may be instructed to irrigate the contact lens with rewetting drops and massage the contact lens prior to blinking the lens out or to remove it with a contact lens suction cup.

Instructions for Removal of the Contact Lens with a Suction Cup:
Place the suction cup near the edge of the contact lens in the 6 o'clock position. Gently rotate the contact lens nasally and temporally to insure the contact lens is movable. Lift the contact lens upward and outward, holding the eye lids away from the cornea. If the contact lens does not easily release from the eye, repeat lens rotation on the eye and rotate the suction cup superiorly and lift the contact lens out of the eye. Alternate as needed until the lens easily releases from the eye.

HANDLING OF THE MENICON Z™ (TISILFOCON A) CONTACT LENS
Conventional methods of putting in contact lenses for regular corneas apply to the **Menicon Z™ (tisilfocon A)** contact lens. Instruct the patient how to put in and remove the contact lens. Make sure the patient is able to put in the contact lenses and remove them before the patient leaves your office.

LENS CARE DIRECTIONS

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

Eye care professional or practitioner 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 and carefully follow instructions on the solution label. Different solutions cannot always be used together, and not all solutions are safe for use with all contact lenses. **Do not alternate or mix lens care systems unless indicated on the product instructions.**
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting contact lenses. Do not put lenses in the mouth.
- The contact lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme (as recommended by the eye care professional or practitioner) and disinfect contact lenses according to the schedule prescribed by the eye care professional or practitioner. The use of an enzyme or any cleaning solution **does not substitute for disinfection**.
- The lens care products listed below are recommended by Menicon for use with the **Menicon Z™ (tisilfocon A)** contact lens. Refer to the package inserts for the products that may be used with the contact lenses. The eye care professional or practitioner may recommend alternate solutions that are appropriate for use with the contact lenses. 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 or practitioner.

Recommended Care System:

Solution Purpose	**Lens Care System** **Chemical (not heat) disinfection**
Cleaning	Menicon Unique pH® Multi-Purpose Solution
Rinsing	Menicon Unique pH® Multi-Purpose Solution, LacriPure or solutions recommended by the eye care professional or practitioner
Disinfection/Storage	Menicon Unique pH® Multi-Purpose Solution
Lubrication/Rewetting	Solutions recommended by the eye care professional or practitioner
Periodic Protein Cleaning	Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses
Use with Scleral Contact Lenses	Sterile non-preserved solution (e.g., LacriPure) or solutions recommended by the eye care professional or practitioner

- Some solutions may have more than one function, which will be indicated on the label. Read the label of the solution, and follow the instructions.
- Always clean the same contact lens first to avoid mix-ups with a recommended cleaning solution. Rinse the contact lens thoroughly with recommended solution to remove the cleaning solution, mucus, and film from the lens surface, and put the contact lens into the correct chamber of the lens case. Then repeat the procedure for the other lens.
- After cleaning, disinfect contact lenses using the system recommended by the manufacturer and/or the eye care professional or practitioner.
- To store contact lenses, disinfect and store them in a closed/unopened lens case until ready to wear. If contact lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care professional or practitioner for information on storage of the contact lenses.
- After removing contact lenses from a lens case, empty and rinse the lens case with sterile contact lens solutions recommended by the lens case manufacturer (never use tap water); then allow the lens case to air dry. When the lens case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or the eye care professional or practitioner.
- The eye care professional or practitioner may recommend a **lubricating/rewetting** solution, which can be used to wet (lubricate) contact lenses while they are being worn to make them more comfortable.
- The **Menicon Z™ (tisilfocon A)** contact lens cannot be heat (thermally) disinfected.

Chemical (Not Heat) Disinfection:
- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse the contact lenses with a recommended rinsing solution.
- To disinfect the contact lenses after cleaning, carefully follow the instructions for the disinfecting solution in the care regimen recommended by the lens manufacturer or the eye care professional or practitioner.
- Thoroughly rinse contact lenses with a recommended fresh saline solution before wearing, or follow the instructions on the disinfection solution label.
- Do not heat the disinfection solution and contact lenses.
- Store the contact lenses in an unopened lens case until ready to wear.
- Contact lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse with fresh sterile saline solution (or follow the instructions on the disinfection solution label) prior to putting in the contact lenses should reduce the potential for irritation.

CARE FOR A STICKING (NON-MOVING) LENS
If the contact lenses stick (stop moving) on the eyes, the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eyes and wait until the lenses begin to move freely on the eyes before removing them. If non-movement of the contact lenses continue for more than 10 minutes, the patient should **immediately** consult the eye care professional or practitioner.

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

Dry shipping of the contact lenses are available upon request.

The foil-sealed plastic container, packing slip or invoice is marked with the information for base curve, diopter power, diameter, center thickness, color, a UV-absorber symbol, serial No., expiration date and other required parameters for the design.

REPORTING OF ADVERSE REACTIONS
All serious adverse experiences and reactions observed in patients wearing the **Menicon Z™ (tisilfocon A)** contact lens should be reported to:

SynergEyes, Inc.
2232 Rutherford Rd
Carlsbad, CA 92008
Tel.: 1-760-476- 9410
FAX: 1-760-476- 9340
www.synergeyes.com

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Menicon Z™

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