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

Contact lens:
- Crystaline lens

Menicon Z™ (tisolfocon A) contact lens:
- Measured by the Hamano Polarographic method.
- Measurement of Dk by Fatt, Polarographic method. (PHEMA Method for determination of oxygen permeability: ISO 8039-2)

PRODUCT NAME LIST
All products in this list are manufactured of Menicon Z™ (tisolfocon A).

- SynergEyes GP
- SynergEyes GP + Bitor
- SynergEyes GP + Bitor Extra
- SynergEyes GP + Bitor Progressive
- SynergEyes GP + Bitor Progressive Plus
- SynergEyes GP + EP
- SynergEyes GP + Bitor Extra Progressive
- SynergEyes GP + Bitor Progressive
- SynergEyes GP + Bitor Progressive Plus
- SynergEyes GP + EP
- SynergEyes GP + EP + Bitor
- SynergEyes GP + EP + Bitor Extra
- SynergEyes GP + EP + Bitor Progressive
- SynergEyes GP + EP + Bitor Progressive Plus
- SynergEyes VS - Sphere
- SynergEyes VS - Toric
- SynergEyes VS - Pseudophakic
- SynergEyes VS - XL - Sphere
- SynergEyes VS - XL - Toric

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 the instructions on the labels for proper use of contact lenses and lens care products, including the lens care products, because unexpected ulcers, can develop rapidly and lead to loss of vision.
- Daily wear contact lenses (such as lenses for irregular corneal conditions, including keratoconus), should not be worn overnight, wear patients should be instructed not to wear contact lenses while sleeping. Clinical studies have shown the risk of developing serious infections increases when daily wear contact lenses are worn overnight.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when containing contact lenses are worn overnight or while sleeping.
- If a patient experiences eye discomfort, excessive tearing, visual changes, or redness and irritation, 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 areas.
- The contact lens users should continue to use their protective UV-absorbing eyewear.
- Never use tap water for the care of the contact lenses and lens care products.
- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If contact lenses have been submerged 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.
- Always use fresh unexpired lens care solutions. The manufacturer's instructions on the disinfecting solution label should be followed. Patients who wear contact lenses to correct presbyopia may not achieve the best-corrected visual acuity for either far or near vision. Wearers should be informed that the most appropriate type of lens for each patient.
- It is advised that wound healing and corneal curvature are established before inserting a contact lens for post-surgical or other compromised corneas.

Menicon Z™ (tisolfocon A) lens contact:
- Measured by the Hamano Polarographic method. (PHEMA Method for determination of oxygen permeability: ISO 8039-2)

- Physicochemical properties of contact lenses materials

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**PRECAUTIONS**

NONTOLERANT, 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, fewer patients in designs, 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 comfort, vision, ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The overall 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 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. Caregivers should be instructed to follow the directions of the eye care professional or practitioner.

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**Solution Precautions**

- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.

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**WARNING**

- Eye care professional or practitioner should instruct patients to remove contact lenses immediately if the eyes become red or painful.
- The use of fluorescein is contraindicated in those patients who have a known hypersensitivity to any component.
- The lenses indicated for wear by the manufacturer are the Menicon Z™ (tisolfocon A) contact lens material which may require equipment enhancement to visualize fluorescein patterns adequately. (Ref to the Menicon Z™ (tisolfocon A) Professional Fitting and Information Guide for detailed instructions.)
- Follow-up visits are necessary to assure the continuing health of the patient's eyes. The eyes should be inspected as indicated by the prescribing eye care professional or practitioner.
- The lens material (tisolfocon A) is a thermoset copolymer derived from fluoro-methacrylate and siliconesxylane, bond 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™ (tisolfocon A) contact lens is a hemispherical shell of the following dimensions (not all parameter combinations are available in all designs):
• 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 exposure to air reduces the ability of the lens surface to return to a wettable state.
• Do not use saliva or anything other than the recommended cleaning or lubricating solution for contact lenses.
• Different solutions cannot always be used together, and not all solutions are safe for use with all contact lenses. Use only the solutions recommended for the lenses you are wearing.
• 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 Wear 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 at least 30 seconds and the patient should be free of discomfort.
• Different solutions cannot always be used together, and not all solutions are safe for use with all contact lenses. Use only the solutions recommended for the lenses you are wearing.
• 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.

Avoid all harmful or irritating vapors and fumes while putting in new contact lenses, the patient may be allergic or sensitive to any of these ingredients. A thorough rinse with fresh sterile saline solution is 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 above solution products listed below are recommended by Menicon for use with the Menicon Z™ (tisolfocon A) contact lens. Refer to the package inserts for the products that are used with the contact lenses. The eye care professional or practitioner may recommend alternate solution products that are appropriate for use with the contact lenses. Care should not be taken to mix solutions from different companies and/or care systems unless specifically instructed to do so by the eye care professional or practitioner.

Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. The eye care professional or practitioner should recommend a schedule that is right for the patient.

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

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 clean and disinfect the lenses before moving freely on the eyes. If non-movement of the contact lenses continues for more than 10 minutes, the patient should immediately consult the eye care professional or practitioner.

EMERGENCIES
The patient should be informed that if chemicals of any kind (household products, gardenings, laboratory chemicals, etc.) are splashed into the eyes, the patient should:

• FLUSH THE EYES IMMEDIATELY WITH TAP WATER or another prescribed disinfecting solution promptly and consult the eye care professional or practitioner or visit a hospital emergency room without delay.

HOW SUPPLIED
• Menicon Z™ (tisolfocon A) contact lens is shipped immersed in Menicon Unique pH® Multi-Purpose Solution (0.0011% polyanquimium-1 and 0.001% 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 container and washed with a fresh saline solution before wearing, or follow the instructions on the disinfecting solution label.

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

Synergeyes, Inc.,
2232 Rutherford Rd,
Carlsbad, CA 92008
Tel.: 1-760-476-9410
Fax: 1-760-476-9040
www.synergeyes.com

Print Date 2018-12-07
LMS0027-02

Tel.: 1-760-476-9410
www.synergeyes.com

Print Date 2018-12-07

Menicon Z™ (tisolfocon A) contact lens cannot be heated (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 disinfesting 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 disinfecting 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 disinfecting 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.

Lens Deposits and Enzymatic Cleaning:
Enzyme cleaning should be recommended by the eye care professional or practitioner. Enzyme cleaning removes protein deposits on contact lenses. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the contact lenses and eyes. If these deposits are not removed, they can damage the contact lenses and cause irritation to the eyes. The eye care professional or practitioner should recommend a schedule that is right for the patient.

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

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• 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 disinfesting 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 disinfecting 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 disinfecting 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.

Lens Deposits and Enzymatic Cleaning:
Enzyme cleaning should be recommended by the eye care professional or practitioner. Enzyme cleaning removes protein deposits on contact lenses. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the contact lenses and eyes. If these deposits are not removed, they can damage the contact lenses and cause irritation to the eyes. The eye care professional or practitioner should recommend a schedule that is right for the patient.

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