

SETTING A NEW STANDARD

# Menicon Z

THE WORLD'S FIRST HYPER Dk/t GP CONTACT LENS  
FDA APPROVED FOR UP TO 30 DAYS CONTINUOUS WEAR

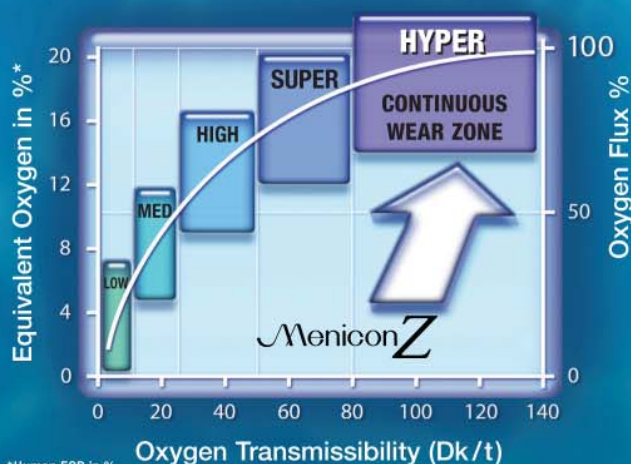


# Menicon Z

Menicon Z is the first GP contact lens to receive FDA approval for up to 30 days continuous wear. The breakthrough hyper Dk/t Menicon Z material surpasses the competition. Menicon Z is the only GP offering extraordinary levels of oxygen transmissibility and excellent physical properties.

## MENICON Z HYPER Dk/t MATERIAL PROVIDES:

- 30 Days Continuous Wear
- Long-Term Corneal Health
- Superior Stability and Wettability
- Excellent Deposit Resistance
- Clear Vision and Enhanced Comfort

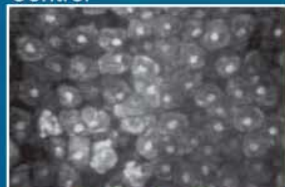


## CONTINUOUS WEAR ZONE

There are 5 categories of oxygen transmissibility (low, medium, high, super and hyper). The hyper category is also known as the "continuous wear zone". This is also the best zone for healthy contact lens wear whether for daily wear or continuous wear. Menicon Z is made of an advanced hyper Dk/t material.

\*Human EOP in %

### Control



## NORMAL CORNEAL EPITHELIAL DESQUAMATION

Research has shown that contact lenses with low to high oxygen transmissibility still cause hypoxia and lead to abnormal epithelial cell desquamation. Desquamation is the shedding of corneal epithelial cells and appears in the photo as the darker areas without cells. Much more transmissibility has been found to be necessary to insure normal epithelial turnover. With the hyper Dk/t Menicon Z, normal desquamation even in the closed eye condition was observed.

### Hyper Dk/t<sup>1</sup> Menicon



### High Dk/t<sup>2</sup>



## MINIMAL ADHERENCE OF *Pseudomonas aeruginosa*

Lower oxygen lenses, soft or rigid, cause a significant amount of *Pseudomonas* binding to corneal epithelial cells. This can lead to a greater incidence of keratitis and ulceration. Recent studies have now clearly demonstrated that eyes fitted with lenses of increasing Dk/t values show diminishing amounts of *Pseudomonas* adherence. Only the Hyper Dk/t Menicon Z demonstrated low adherence levels similar to the control in overnight studies.



Lens Center Thickness (-3.00D)

1. Menicon Z .13mm
2. Menicon Super EX (SF-P) .18mm
3. Menicon EX .15mm
4. Menicon O2-32 (SP) .15mm

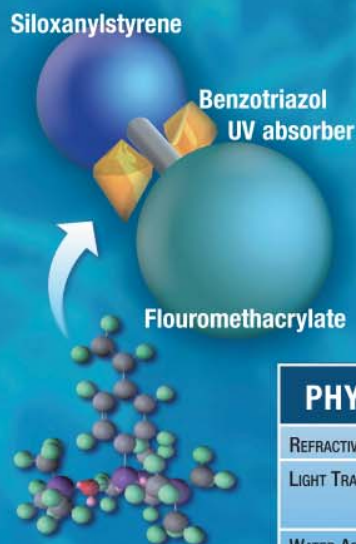


FDA APPROVED FOR UP TO  
**30 DAYS**  
 CONTINUOUS WEAR

UNIQUE **Menicon Z** MATERIAL

The unique polymer chemistry results in excellent physical properties, allowing this lens to be made significantly thinner, comparable to a medium Dk/t lens.

- Hyper Oxygen Transmissibility
- Durability
- Stability
- UV Filter
- Thin Design
- Excellent Deposit Resistance



**PHYSICAL/OPTICAL PROPERTIES**

REFRACTIVE INDEX	$n_D^{20}$ 1.440
LIGHT TRANSMITTANCE	$\geq 90\%$ (380 to 780nm, 0.1mm sample thickness) $\leq 5\%$ (210 to 380nm, 0.1 mm sample thickness)
WATER ABSORPTION	Less than 0.5% by weight (25°C)
SPECIFIC GRAVITY	1.20 (25°C)
OXYGEN PERMEABILITY	$163 \times 10^{-11}$ (cm <sup>2</sup> /sec) · (mlO <sub>2</sub> /(ml × mmHg)) * $189 \times 10^{-11}$ (cm <sup>2</sup> /sec) · (mlO <sub>2</sub> /(ml × mmHg)) **

\* Method for determination: ISO 9913.1:1996

\*\* Measurement of Dk by the Fatt polarographic method without edge effect correction

**MATERIAL STRENGTH**

To measure impact strength of GP material, a steel ball (11.9 mm diameter/6.9g) is dropped on a sample lens (0.2mm parallel thickness). The height of the dropped ball is recorded when the lens breaks. The Menicon Z material showed superior impact strength and rigidity compared to lower category GP lenses.



Impact Strength (cm)

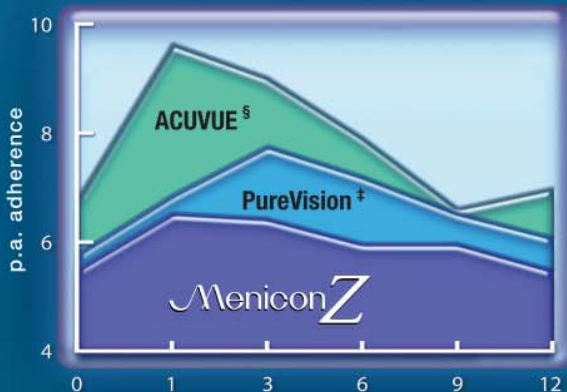
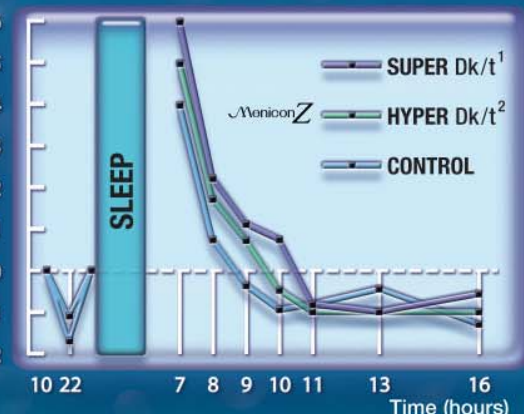


\*\*Measurement of Dk by the Fatt polarographic method without edge effect correction

**REDUCED CORNEAL SWELLING**

In a study that demonstrated corneal swelling during overnight lens wear, hyper Dk/t Menicon Z lenses were compared to lenses of lower Dk/t values. The results showed that corneal swelling was the lowest with Menicon Z. Moreover, the results were nearly identical to normal corneal swelling without contact lenses.

Corneal Swelling (%)



**COMPARISON OF PSEUDOMONAS ADHERENCE<sup>†</sup>**

When the Menicon Z lens was compared to Acuvue<sup>TM§</sup>, a high Dk/t 7-day EW hydrogel lens, and PureVision<sup>TM†</sup>, a hyper Dk/t 30-day CW silicone hydrogel lens, Menicon Z showed the least amount of Pseudomonas adherence. Menicon Z demonstrated superb physiologic performance even surpassing the silicone hydrogel lens in this comparison. Whether for daily wear or up to 30 days Continuous Wear, Menicon Z represents a truly superb choice for safety and convenience for your patients.



# Menicon Z

The choice is now yours. Menicon Z delivers a high standard of convenience and safety for your patients, whether they are candidates for daily wear, occasional extended wear, 7-day extended wear or up to 30 days continuous wear. Approved designs include spherical, aspheric, custom toric and multifocal.

- 30 Days Continuous Wear
- Unique Hyper Dk/t Material
- Superior Stability and Wettability
- Long-Term Corneal Health
- Clear Vision & Enhanced Comfort
- Easy to Fit

Menicon Z INITIAL BASE CURVE SELECTION (Alpha design)			
CORNEAL ASTIGMATISM	8.8MM DIAMETER	9.2MM DIAMETER	9.6MM DIAMETER
0 to 0.75 D	on K <sub>flat</sub>	0.25 D FTK <sub>flat</sub>	0.50 D FTK <sub>flat</sub>
1.00 to 1.75 D	0.25 D STK <sub>flat</sub>	on K <sub>flat</sub>	0.25 D FTK <sub>flat</sub>
2.00 to 2.50 D	0.50 D STK <sub>flat</sub>	0.25 D STK <sub>flat</sub>	on K <sub>flat</sub>
over 2.50 D	Recommend toric	Recommend toric	Recommend toric

## About Menicon

Menicon Co., Ltd. ([www.menicon.com](http://www.menicon.com)), founded by Mr. Kyoichi Tanaka in 1951, is Japan's first and largest contact lens manufacturer, and now is represented in over 30 countries. Menicon is a manufacturer dedicated to all areas of soft and GP contact lens related businesses including material development, lens designing, and manufacturing of contact lenses and care solutions. Menicon is a world leader in the development of hyper-Dk GP (Menicon Z).



MeniCare GP Lens Care System is recommended for Menicon Z and is an excellent care system for all other GP lenses as well.



Progent is an in-office GP protein remover for professional use only.

**Intended Use:** Menicon Z™ (Bifilococon A) contact lenses are indicated for daily wear or up to 30 days continuous wear. The lens may be prescribed in spherical and aspheric design and powers ranging from -25.00 D to +25.00 D for daily wear and 25.00 D to +8.00 D for extended wear. Toric lenses designed to correct up to 5.00 D of astigmatism and multifocal lenses providing up to +3.00 D of reading add power are available for daily and extended wear.

In addition to a complete listing found in the Package Insert, the following warning, precautions, contraindications and side effects are particularly relevant to this device:

**Warning:** The risk of serious ocular complications is greater for extended wear as compared to daily wear and smoking increases these risks. The risk among extended wear lens users increases with the number of consecutive days lenses are worn between removals beginning with the first overnight use. It is essential that patients follow their eye care professional's direction and all labeling instructions for proper use of lenses, lens case and lens care products. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. The long-term risk of microbial keratitis has not been determined for this lens. Post-marketing studies are in progress.

**Precautions:** Not all patients can achieve the maximum wearing time of up to 30 Days continuous wear. Patients should be carefully evaluated for continuous wear and eye care professionals should conduct early and frequent follow-up examinations to determine the maximum wearing time based upon the individual patient's physiological response and lens performance on the eye. During the U.S. clinical study, 516 of the 634 eyes dispensed completed the full year of lens wear with average wearing times of 22 days or more for 66.5% of all visits after 1 month. When selecting an appropriate lens and wear schedule for a patient, the eye care professional should consider all lens characteristics that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. Thin lens designs should always be considered when fitting patients for extended wear.

**Contraindications:** Lenses should not be used by patients when an inflammation or infection of the eye is present or with a disease or injury in or around the eye. The lenses should not be used by patients who have medical conditions or who are taking medication that might interfere with contact lens wear.

**Side effects:** Infiltrative keratitis was reported at a rate of about 0.6% for the 317 subjects during the one-year U.S. study. In total, about 6.0% of the subjects experienced one or a combination of moderate or severe events, including superficial corneal changes, corneal swelling or changes to the eyelid lining, in both daily and extended wear, neovascularization and palpebral conjunctival abnormalities were noted more often in soft lens wearers, with 3 & 9 o'clock staining noted more often in GP lens wearers.

† Ren, Yamamoto, et al. Ophthalmology 109(1):27-39, 2002. § Acuvue is a registered trademark of Johnson & Johnson Vision Care, Inc. ‡ PureVision is a registered trademark of Bausch & Lomb



Menicon America, Inc. • San Mateo, CA 94404 USA • [www.menicon.com](http://www.menicon.com)