

1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM (etafilcon A)
Visibility Tinted with UV Blocker for Daily Wear

SYMBOLS KEY

The following symbols may appear on the labels or cartons:

SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
	Diameter
	Base Curve
	Diopter (lens power)
	Quality System Certification Symbol
	UV-Blocking
	Fee Paid for Waste Management
	Peel Back Foil
	CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Center Thickness
	Lens Orientation Correct
	Lens Inside Out
	Consult Instructions for Use
	Manufactured by or in
	Cylinder Power
	Axis

Toric Lenses for:
Myopic Astigmatism,
Hyperopic Astigmatism,
phakic or aphakic

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

The physical/optical properties of the lens are:

- Specific Gravity (calculated): 0.98 - 1.12
- Refractive Index: 1.40
- Visible Light Transmission: 85% minimum, visibility tint 95% minimum, clear

- Surface Character: Hydrophilic
- Water Content: 58%
- Oxygen Permeability:

VALUE	METHOD
28.0 x 10-11(cm2/sec)	Fatt (boundary corrected, non-edge corrected)
(ml O2/ml x mm Hg) at 35°C	Fatt (boundary corrected, edge corrected)
21.4 x 10-11(cm2/sec)	
(ml O2/ml x mm Hg) at 35°C	

The 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM are hemitorical shells of the following dimensions:

Diameter:(12.0 mm to 15.0 mm)

Center Thickness: low minus lens - varies with power (e.g., -3.00D: 0.090mm) plus lens - varies with power (e.g., +3.00D: 0.176mm)

Base Curve: (7.85mm to 10.00mm)

Power: Daily Wear -20.00D to +20.00D
Cylinder Power: -0.25D to -10.00D
Axis: .25° to 180°

Available Lens Parameters		
Base Curve	Diameter	Power Range
Minus		
8.5mm	14.5mm	Plano to -6.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments) Cylinders -0.75D, -1.25D, -1.75D Axis 10°, 20°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 160°, 170°, 180°
8.5mm	14.5mm	Plano to -6.00D (in 0.25D increments) -6.50D to -9.00D (in 0.50D increments) Cylinder -2.25D Axis 20°, 90°, 160°,180°

- medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
 - As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

- Who Should Know That the Patient is Wearing Contact Lenses?
- Inform the doctor (Health Care Professional) about being a contact lens wearer.
 - Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

ADVERSE REACTIONS

- The patient should be informed that the following problems may occur when wearing contact lenses:
 - The eye may burn, sting and/or itch.
 - There may be less comfort than when the lens was first placed on the eye.
 - There may be a feeling of something in the eye (foreign body, scratched area).
 - There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers or corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
 - There may be excessive watering, unusual eye secretions, or redness of the eye.
 - Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn continuously or for too long a time.

- The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:
- How do the lenses feel on my eyes?
 - How do my eyes look?
 - Do I continue to see well?

If the patient reports any problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS.

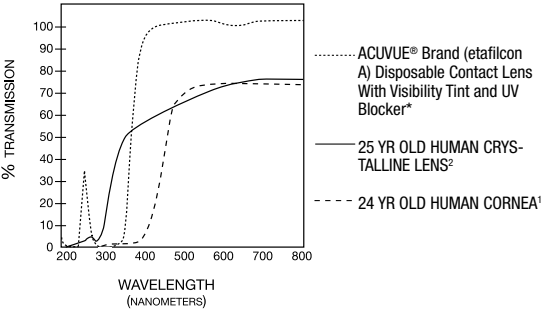
If the discomfort or problem stops, the patient should then look closely at the lens.

If the lens is in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and insert a new fresh lens on the eye.

Plus		
8.5mm	14.5mm	+0.25D to +4.00D (in 0.25D increments) Cylinders -0.75D, -1.25D, and -1.75D Axis 20°, 70°, 90°, 110°,160°, 180°

TRANSMITTANCE CURVE

ACUVUE® Brand (etafilcon A) Contact Lens Visibility Tinted with UV Blocker, 24 yr. old human cornea and 25 yr. old human crystalline lens



*The data was obtained from measurements taken through the central 3-5mm portion for the thinnest marketed lens (~1.00D lens, 0.085mm center thickness).

1. Lerman, S., Radiant Energy and the eye, MacMillan, New York, 1980, p.58, figure 2-21

2. Waxler, M., Hitchens, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.10, figure 5

WARNING: UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

ACTIONS

In its hydrated state, the 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The average UV Blocking is:	UVA 82%	UVB 97%
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If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, he or she should be instructed to dispose of the lens and insert a new fresh lens.

If the problem continues, the patient SHOULD NOT put the lens back on the eye BUT IMMEDIATELY CONSULT HIS OR HER EYE CARE PROFESSIONAL.

The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. He or she should be instructed to seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING GUIDELINES

GENERAL FITTING INSTRUCTIONS

- A. Patient Selection:
- Patients selected to wear 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM (etafilcon A) should be chosen based on:
- Motivation to wear lenses
 - Ability to follow instructions regarding lens wear care
 - General health
 - Ability to adequately handle and care for the lenses
 - Ability to understand the risk and benefits of lens wear.
 - An appropriate and usual physiological and diagnostic assessment should be conducted to ensure proper patient selection.
 - Patients who do not meet the above criteria should not be provided with contact lenses.

B. Pre-fitting Examination

Initial evaluation of the patient should begin with a thorough case history to determine if there are any contraindications to contact lens wear. During the case history, the patient's visual needs and expectations should be determined as well as an assessment of their overall ocular, physical, and mental health.

Preceding the initial selection of trial contact lenses, a comprehensive ocular evaluation should be performed that includes, but is not limited to, the measurement of distance and near visual acuity, distance and near refractive prescription. Collect and record baseline clinical information to which post-fitting examination results can be compared.

Based on this evaluation, if it is determined that the patient is eligible to wear the 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM, the Eye Care Professional should proceed to the appropriate lens fitting instruction outlined below.

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 blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

INDICATIONS (USES)

The 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM are indicated for daily disposable wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes who are hyperopic or myopic and may have 0.50D to 3.00D of astigmatism.

The 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM help protect against transmission of harmful UV radiation to the cornea and into the eye.

CONTRAINDICATIONS (REASONS NOT TO USE)

- DO NOT USE the 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM when any of the following conditions exist:
- Acute or subacute inflammation or infection of the anterior chamber of the eye
 - Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
 - Severe insufficiency of lacrimal secretion (dry eyes)
 - Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic
 - Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
 - Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
 - Any active corneal infection (bacterial, fungal, protozoal or viral)
 - If eyes become red or irritated

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses or lens care products could result in serious injury to the eye. Patients should be cautioned that proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products.
- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.

C. Initial Power Determination

A spectacle refraction should be performed to establish the patient's baseline refractive status and to guide in the selection of the appropriate lens power. Remember to compensate for vertex distance if the sphere or the combined sphere and cylinder refraction is greater than ±4.00D.

D. Base Curve Selection (Trial Lens Fitting)

In clinical tests, the 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM 8.5mm/14.5mm Contact Lenses have performed successfully on eyes with a range of keratometry readings. However, corneal curvature measurements should be performed to establish the patient's baseline ocular status.

A 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM (etafilcon A) 8.5mm/14.5mm lens should be placed on each of the patient's eyes and evaluated after the patient has adjusted to the lenses.

- Criteria of a Properly Fit Lens
A properly fit lens will center and completely cover the cornea (i.e., no limbal exposure), have sufficient movement to provide tear exchange under the contact lens with the blink and be comfortable. The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.
- Criteria of a Flat Fitting Lens
A flat fitting lens may exhibit one or more of the following characteristics: decentration, incomplete corneal coverage (i.e., limbal exposure), excessive movement with the blink and/or edge standoff. If the 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM (etafilcon A) 8.5mm/14.5mm Contact Lens is judged to be flat fitting, it should not be dispensed to the patient.
- Criteria of a Steep Fitting Lens
A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation and resistance when pushing the lens up digitally with the lower lid. If the 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM (etafilcon A) 8.5mm/14.5mm Contact Lens is judged to be steep fitting, it should not be dispensed to the patient.

E. Final Lens Power

When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, a spherocylindrical over-reaction may be performed

- The overall annual incidence of ulcerative keratitis in daily wear contact lens users is estimated to be about 4.1 per 10,000 persons and about 20.9 per 10,000 persons in extended wear contact lens users.
- The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact lens users than for daily wear users.' When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily basis are excluded from the comparison, the risk among extended wear users is 10 to 15 times greater than among daily wear users.
- When daily wear users wear their lenses overnight (outside the approved indication),the risk of ulcerative keratitis is 9 times greater than among those who do not wear them overnight.
- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- The risk of ulcerative keratitis among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.

If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Professional. It is recommended that contact lens wearers see their Eye Care Professional routinely as directed.

Special Precautions for Eye Care Professionals:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness and optic zone diameter. The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.
- Patients who wear the 1-DAY ACUVUE® MOIST® Brand Contact Lenses for ASTIGMATISM to correct presbyopia using monovision 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.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

1 New England Journal of Medicine, September 21, 1989

and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the spectacle cylinder axis, it is not advisable to over-refract because of the difficulty in computing the resultant power.

In fitting contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible. So, here is how to determine the final lens power.

For the Sphere:

If sphere alone or combined sphere and cylinder Rx ≥±4.00D, compensate for vertex distance. If sphere alone or combined sphere and cylinder Rx ≤±4.00D, vertex compensation is not necessary.

For the Cylinder:

Adjust the axis by the drift angle using LARS. Choose a cylinder that is ≤0.50D from the refractive cylinder.

Case Examples

Example 1:	Manifest (spectacle) refraction: O.D. -2.50 -1.25 x 180 20/20 O.S. -2.00 -1.00 x 180 20/20
	Choose a diagnostic lens for each eye with an axis as close to 180° as possible. Place the lens on each eye and allow a minimum of 1 minute for it to equilibrate, based on the patient's initial response to the lens.
	Check the orientation of the axis mark. If the bottom axis mark is in the 6 o'clock position on both eyes, choose the appropriate cylinder as listed previously.
	Here is the Rx Prescribed/Ordered: O.D. -2.50 -1.25 x 180 O.S. -2.00 -0.75 x 180
Example 2:	Manifest (spectacle) refraction: O.D. -3.00 -1.00 x 90 20/20 O.S. -4.75 -2.00 x 90 20/20

Choose a diagnostic lens of -3.00 -0.75 x 90 for the right eye and -4.50 -1.75 x 90 for the left eye, the nearest lenses available to the spherical power and axis needed. Place the lens on each eye and allow a minimum of 1 minute for it for it to equilibrate.