PROFESSIONAL FITTING AND INFORMATION GUIDE

midafilcon A (56% water) for Daily Disposable Soft Contact Lens

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

DESCRIPTION

midafilcon A (56% water) is a daily wear soft silicone hydrogel contact lens and intended for single use. It is available in spherical, toric and multifocal lens designs.

The non-ionic lens material (midafilcon A) is a random co-polymer containing polydimethyl siloxane macromonomer. It consists of 44% midafilcon A and 56% water by weight when it is immersed in buffered saline solution. The lens is blue tinted for visibility.

The lens contains a benzotriazole UV absorbing monomer which blocks UV radiation. The transmittance characteristics for the lens (-3.00 D) are less than 5% of UVB radiation and less than 50% of UVA radiation.

The contact lenses are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera with the following dimensions:

Spherical Contact Lens	
Diameter	14.2 mm
Center Thickness	0.07 mm to 0.25 mm
Base Curve	8.4 mm
Powers	+6.00 to +0.250 D (0.25 D steps) -0.25 to -6.00 D (0.25 D steps) -6.50 to -13.00 D (0.50 D steps)
Toric Contact Lens	
Diameter	14.2 mm
Center Thickness	0.08 mm to 0.13 mm
Base Curve	8.4 mm
Powers	0.00 to -6.00 D (0.25 D steps) -6.50 to -10.00 D (0.50 D steps)
Cylinder Power	-0.75 D, -1.25 D, -1.75 D
Axis	10°, 20°, 90°, 160°, 170°, 180°
Multifocal Contact Lens	
Diameter	14.2 mm
Center Thickness	0.07 mm to 0.23 mm
Base Curve	8.4 mm
Powers	+5.00 to -6.00 D (0.25 D steps) -6.50 to -10.00 D (0.50 D steps)
Add Power	+1.00 D (LOW), +2.00 D (HIGH)

The physical properties of the contact lenses are:
Refractive Index: 1.403
Surface Character: Hydrophilic
Light Transmittance: >92%
Specific Gravity: 1.06
Water Content: 56%
Oxygen Permeability: 64 x 10^{-11} (cm^2/sec) (mL O_2/(mL x mm Hg))

ACTIONS

The **midafilcon A (56% water)** contact lens acts as a refracting medium to focus light rays on the retina when put on the cornea in its hydrated state.

INDICATIONS

The **midafilcon A (56% water) spherical** contact lens is intended for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic disease-free eyes.

The **midafilcon A (56% water) toric** contact lens is intended for the correction of refractive ametropia (myopia and astigmatism) in aphakic and non-aphakic disease-free eyes.

The **midafilcon A (56% water) multifocal** contact lens is intended for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic disease-free eyes.

The **midafilcon A (56% water)** contact lenses are intended to be worn only once and then discarded after a single day of wearing. The daily disposable contact lenses are not intended to be cleaned or disinfected. Instruct patients to follow the wearing period determined by eye care professionals or practitioners.

The daily wear contact lenses are designed to be worn for less than 24 hours while awake. The maximum wearing time should be determined by eye care professionals or practitioners based upon patient's physiological eye condition since individual responses to contact lenses vary. Patients initially tend to wear contact lenses longer than they should. Eye care professionals or practitioners should emphasize the importance of adhering to the initial maximum wearing schedule.

Studies have not been conducted to show that the **midafilcon A (56% water)** contact lens is safe to wear during sleep. Clinical studies have shown that risk of serious adverse reactions is increased when daily wear contact lenses are worn during sleep; therefore, the lenses should be removed before sleeping.

Generally, at lease 6 hours of non-wearing contact lenses per 24 hours is assumed. However, optimum wearing schedule will vary for each individual.

CONTRAINDICATIONS

Do not use the **midafilcon A (56% water)** contact lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eyes
- Any disease, injury, or abnormality that affects the cornea, the conjunctiva or eyelids
- Severe lacrimal secretion insufficiency (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if non-aphakic
- Any systemic disease that may adversely affect the eyes by wearing contact lenses
- Allergic reactions that may be induced or exaggerated by wearing contact lenses and/or using lens care solutions
- Any active corneal infection
- Red or irritated eyes
- Incomplete corneal healing following eye surgery
- The patient is unable to follow the lens wearing schedule or unable to obtain assistance to do so.

WARNINGS

Please read "WARNINGS" in Package Insert for the **midafilcon A (56% water)** contact lens.

PRECAUTIONS

Please read "PRECAUTIONS" in Package Insert for the **midafilcon A (56% water)** contact lens.

ADVERSE REACTIONS

Please read "ADVERSE REACTIONS" in Package Insert for the **midafilcon A (56% water)** contact lens.

PATIENT SELECTION

Do not prescribe the **midafilcon A (56% water)** contact lens to patients who cannot adhere to the recommended wearing schedule. Review Package Insert for the **midafilcon A (56% water)** contact lens with patients and have them understand all necessary precautions and warnings.

FITTING PROCEDURE

Pre-fitting Examination

Paitent history and pre-fitting examination are necessary to:

- Determine whether a patient is suitable for wearing daily wear contact lenses (refer to "CONTRAINDICATIONS").
- Make ocular measurements for initial contact lens parameter selection.
- Record baseline clinical information to be compared to post-fitting examination results.

1. Initial Lens Power Selection

For spherical lens:

- Determine lens power from patient's spherical equivalent prescription corrected to the corneal plane.
- Select an appropriate power contact lens and put it in the eye. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a equilibrium state.

For toric lens:

- Determine lens power from the patient's best spherical-cylindrical refraction. Select a spherical power based on the refraction with vertex compensation, and a cylindrical power using the same compensation for meridional power.
- Select an appropriate trial lens and put it in the eye with the guide mark pointing down. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a equilibrium state.

For multifocal lens:

- Determine distance lens spherical power from patient's spherical equivalent prescription corrected to the corneal plane. Select initial add power referring to the add power prescribed for the patient's eyeglasses.
- Select an appropriate power contact lens and put it in the eye. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a equilibrium state.

2. Initial Lens Evaluation

- Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics. Wait until the increase in tear flow subsides and then evaluate the contact lens. The required time varies with individuals.
- To determine proper lens parameters, use a slip lamp to observe the lens in the eye.
  - Position/centration: The lens should fully cover the cornea.
  - Movement/stability: The lens should discernibly move with a primary gaze blink, upward gaze blink, and upward gaze lag.
  - Toric lens rotation: The lens should position with a guide mark on the lens pointing down when the lower eye lid is pulled down. Carefully examine blinks and note the mid-blink resting location, the amount and direction of rotation by a blink, and the time that takes for the lens to return to its resting position after a blink.

3. Final Power Determination

For spherical lens:
Determine spherical over refraction to obtain the best corrected visual acuity.

For toric lens:
Determine spherical-cylindrical over refraction to obtain the best corrected visual acuity. If off axis location is noted during the lens position/movement and stability evaluation, a lens with the cylindrical axis that compensates for the off axis rotation may be required. When determining the amount of cylinder for a lens that exhibits moderate inter-blink movement, the eye care professional or practitioner may consider reducing the cylindrical correction and ordering a partial spherical equivalent power to reduce visual acuity fluctuation between blinks.

For multifocal lens:
Examine the distance, intermediate and near vision binocularly and monocularly. Make adjustments in power if necessary.

4. Specific Instructions for Presbyopic Patients

Provide specific instructions, explanations and demonstrations to patients for their optimum wearing of the **midafilcon A (56% water)** multifocal contact lens. Provide patients the following information.

- A contact lens that has distinct lens powers for distance and near visions is technologically and optically more complex than a bifocal or multifocal eyeglass lens. This is because the contact lens moves with the eye, whereas the eyeglass lens remains suspended in a frame while the eye moves up and down. The contact lens gives an unobstructed field of view and greater freedom in where to look, however, the sharpness of vision may not always be exactly the same as it is experienced with eyeglasses.
- Although the **midafilcon A (56% water)** multifocal contact lens can be worn full-time, some patients prefer to wear eyeglasses in some activities. This is an entirely normal and natural response to the Fitting Guide 9 challenges presented by presbyopia.
- Vision with multifocal contact lenses may be less sharp than or different from it is experienced with eyeglasses in situations such as low illumination, poor visibility (e.g., in a fog or heavy rain), and isolated bright light source (e.g., headlights of an oncoming vehicle). Instruct patients to have sufficient lighting for reading fine print.
- Advise patients to refrain from wearing the contact lenses while driving, flying an airplane or operating heavy machinery until they experience wearing the lenses in a similar visual environment.
- Small changes in lens power can make a great difference in the vision experienced with multifocal contact lenses. Tailor such changes to the patient's needs only after the contact lenses are worn in tasks or conditions that the patient encounters on a daily basis. Confidence and assurance that such refinements can be achieved is important for patient motivation during the initial period of wearing the lenses.

CLINICAL ASSESSMENT

1. Criteria of a Well-Fitting Contact Lens

A well-fitting contact lens centers easily after a blink, bridges the limbus and extends onto the sclera approximately 1.25 mm, lags downward approximately 1.0 to 1.5 mm on upward gaze and does not move excessively by a blink or exaggerated eye movements.

After the trial lens has settled on the eye (10 to 20 minutes), manipulate the lens using eyelid pressure and observe for indications of excessive tightness. The lens should move freely and easily with slight pressure and return to the centered position when released.

Movement of the lens on the eye is important in assessing the fit and performance of the lens. In primary gaze, slight vertical lens movement should occur after a blink. On upward gaze, the lens should sag approximately 1.0 to 1.5 mm. Rotation of the lens by a blink should demonstrate adequate movement and be stable enough to maintain vision.

2. Characteristics of a Tight-Fitting Contact Lens

A tight-fitting (steep) contact lens does not move easily on the cornea with slight pressure.

3. Characteristics of a Flat-Fitting Contact Lens

A flat-fitting (loose) contact lens sags more than 2.0 mm on upward gaze.

FOLLOW-UP CARE

- Follow-up examinations, as recommended by eye care professionals or practitioners, are necessary to assure the continued success in wearing the contact lenses.
- Ask patients to wear the contact lenses at least one continuous hour prior to a follow-up examination and identify any problems related to wearing the lenses at the visit.
- With contact lenses in the eyes, evaluate fitting performance to assure that the lenses satisfy characteristics of a well-fitting contact lens. Closely examine surface deposition and/or damage on the contact lenses.
- After removing the contact lenses, 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 unclean contact lenses, a reaction to solution preservatives, wearing contact lenses for too long, and/or poor lens fitting.
- Papillary conjunctival changes can be indicative of unclean and/or damaged contact lenses.

If abnormality is identified in any of the above observations, 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 in any follow-up examinations, fit the patient with a more appropriate contact lens.

FOLLOW–UP EXAMINATIONS

Schedule follow-up examinations:

- Within one week of contact lens dispensing
- After three weeks of wearing contact lens
- After seven weeks of wearing contact lens
- After each six-month period of wearing contact lens

MONOVISION CONTACT LENS FITTING GUIDELINES

1. Patient Selection

Monovision Needs Assessment:

- For a good prognosis, distance and near visual acuity of each eye should be adequately corrected. The **midafilcon A (56% water)** spherical and toric contact lenses can be used for the monovision correction. Monovision with the **midafilcon A (56% water)** contact lens may not be suitable for amblyopic patients.
- Consider occupational and environmental visual demands. If a patient requires critical vision (visual acuity and stereopsis), determine whether the patient can function adequately with monovision by a trial. Wearing monovision contact lenses may not be optimal for such activities as:
  - Visually demanding operations such as dangerous machinery or other hazardous activities
  - Advise patients who cannot pass driver's license requirements with monovision correction that they should not drive with the contact lens or may require that additional correction be prescribed.

2. Patient Education

Monovision correction do not function well with all patients. Patients may not perform certain tasks with monovision correction as they do with bifocal reading eyeglasses. Have patients understand that monovision correction has advantages of clear near vision in straight ahead and upward gazes, and disadvantages that may reduce visual acuity and depth perceptioin as other presbyopic contact lenses or other alternative.

3. Eye Selection
Generally, correct the non-dominant eye for near vision. Perform the following to test for eye dominance.

- Ocular preference determination methods:
  - Method 1: Determine the dominant (sighting) eye. Have a 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 eye.
  - Method 2: Determine which eye will accept an added power with the least reduction in vision. Place a trial near add spectacle lens in front of one eye and then in front of the other eye and perform distance refractive error correction for each eye. Determine which eye (right or left) is suited to use a near add lens for the patient to function most effectively.
- Refractive error method:
  For anisometropic correction, it is generally best to fit the hyperopic (less myopic) eye for distance and the myopic (less hyperopic) eye for near.
- Visual demand method:
  Consider the patients' occupation to determine the critical vision requirements. If a patient usually gazes in one direction for near tasks, correct the eye on that side for near (e.g., for a secretary who usually places copy to the left side of the desk, correct the left eye for near).

4. Special Fitting Considerations
Unilateral lens correction:
Some patients require only one contact lens, such as those with emmetropia who require only a near lens and those with bilateral myope who require only a distance lens.
For 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 -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye, would have the right eye corrected for distance and the left eye uncorrected for near.

5. Near Add Determination
Prescribe a lens power for the near eye that provides optimal near acuity at the midpoint of the patient's reading distance. If more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

6. Trial Lens Fitting
Perform a trial lens fitting in the office to have patients experience monovision correction. Fit contact lenses according to the directions in the general fitting guidelines described in this document.

Consider case history and use standard clinical evaluation procedure to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Then determine the near add power. Observe the reaction to the correction using trial lenses of proper power.

Immediately after putting in correct power contact lenses, have a patient walk across the room and look at you. Assess the patient's reaction to distance vision under the circumstance. Then have the patient look at near objects such as a watch face or fingernails, and assess the reaction. Observe reactions as the patient look at both near and distance objects in the room. After these tasks are completed, have the patient read print. Assess the patient's reaction to large print (e.g., typewritten copy) at first, and then news print, and finally smaller sizes.

After the performance above is completed, test visual acuity and reading ability under conditions of moderately dim illumination.
Although an initial unfavorable response in the office can be indicative of poor prognosis, do not immediately rule out a more extensive trial under usual conditions for the patient.

7. Adaptation
Wearing the contact lenses in visually demanding situations should be avoided during the initial wearing period. Some patients may experience mild blurred vision, dizziness, headaches, and a feeling of slight imbalance at first. Explain the adaptational symptoms to 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 process, advise patients to first use the contact lenses in a comfortable, familiar environment such as at home.

Some patients feel discomfort in wearing contact lenses during driving an automobile in the adaptation period, particularly when driving at night. It is recommend that a patient be a passenger until the vision becomes optimal for operating an automobile. Advise patients to only drive under optimal driving conditions during the first several weeks of the adaptation period. After successful adaptation to driving under optimal conditions, patients should be able to drive with caution under other conditions.

8. Other suggestions
Have patients follow the suggestions below for success of the monovision correction.

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- Have supplemental eyeglasses to wear over the monovision contact lenses for specific visual tasks (this is particularly applicable for patients who cannot meet driving license requirements with monovision correction).
- Use proper illumination when performing visual tasks.

Fitting monovision correction can be improved by the following:

- Reverse the distance and near eyes if a patient has trouble in adaptation.
- Refine lens powers if a patient has trouble in 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.

Eye care professionals or practitioners should determine with patients whether to fit the patient with monovision correction after carefully considering the patient's needs.

Supply all patients with a copy of Patient Instructions for the **midafilcon A (56% water)** contact lens.

HANDLING THE CONTACT LENSES (IN-OFFICE)

- Do not open the blister package until ready for use to assure the sterility.
- Wash and rinse hands thoroughly before handling contact lenses. Make sure that all soap residues have been rinsed away, and then dry hands with a lint-free towel.
- Always handle the left and right contact lenses in the same sequence to avoid mixing up the lenses.
- Carefully pick up the contact lens from the container and examine it to be sure that it is free of any damage or foreign bodies.
- Avoid touching the inside surface (concave side) of the contact lenses.
- Place a contact lens on the tip of the forefinger and examine its profile to make sure it is not turned inside out. If the edge of the contact lens points outward, the lens is inside out.
- Wet contact lenses with lubricant before removal.
- Do not reuse the **midafilcon A (56% water)** contact lens in diagnostic procedures.

CLEANING
Eye care professionals or practitioners should review with patients, lens care directions for cleaning, disinfection and storing, including basic lens care information and specific instructions on the lens care regimen recommended for the patients.

Emergency lens cleaning and disinfection are not recommended. Remind patients to have replacement contact lenses or eyeglasses available at all time.

WEARING SCHEDULE
Provide close professional supervision to patients to ensure safe and successful wearing of the contact lenses. If a patient complains of discomfort, reduced visual acuity, ocular injection or corneal edema, instruct the patient to remove the contact lenses and schedule an examination for the patient. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting contact lenses.

Patients initially tend to wear contact lenses longer than they should. Eye care professionals or practitioners should emphasize the importance of adhering to the initial maximum wearing schedule. Regular check-up examinations, as determined by eye care professionals or practitioners, are important to assure the continued health of the eyes.
The suggested maximum wearing time for the contact lenses is:

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

Studies have not been conducted to show that the midafilcon A (56% water) contact lens is safe to wear during sleep.

REPLACEMENT SCHEDULE
The **midafilcon A (56% water)** contact lens is intended to be worn once and then discarded at the end of each wearing period. Instruct patients to start the next wearing period with fresh lenses.

CARE FOR STICKING (NON-MOVING) CONTACT LENSES
If the contact lenses stick (stop moving or cannot be removed) 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 can move freely on the eyes before removing them. If the discomfort still continues, the patient should **immediately** consult an eye care professional or practitioner.

REPORTING ADVERSE REACTIONS
Eye care professionals or practitioners should report all adverse reactions observed in patients wearing the **midafilcon A (56% water)** contact lens within 5 days to:

Menicon America, Inc.
North Billerica, MA 01862
1-800-MENICON (1-800-636-4266)
www.meniconamerica.com
information@menicon.com

HOW SUPPLIED
The **midafilcon A (56% water)** contact lens is packed to always present the convex side up upon opening to ensure correct lens orientation when putting in the lenses in the eyes.

Each lens is immersed in buffered saline solution in a blister pack. Each container is marked with base curve, dioptric power, diameter, cylinder power (for toric lens), axis (for toric lens), add power (for multifocal lens), brand name, color, See Instructions for Use Symbol, Single Use Symbol, Rx Symbol, Sterile Symbol, lot number and expiration date. The package is marked with the name and address of manufacturer, product and material name, base curve, dioptric power, diameter, cylinder power (for toric lens), axis (for toric lens), add power (for multifocal lens), number of contact lenses, character of storage solution, contents, explanation on daily wear, single use only, Sterile Symbol, lot number, expiration date, See Instructions for Use Symbol, color, Rx Symbol, and UDI code.

HOW TO OPEN

1. Hold the blister strip as shown in the illustration and detach one container. (See Fig.1.)
2. Remove the container foil to open the package. (See Fig.2.)
3. Find one contact lens with the convex side facing up in the container.
4. Carefully pick up the lens from the container and examine it to be sure that it is free of any damage or foreign bodies. (See Fig.2.)

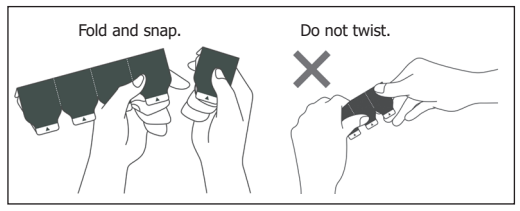

Fig.1

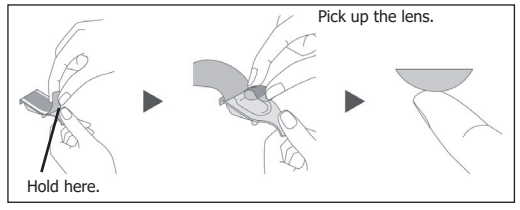

Fig.2

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