IMPORTANT: Please read carefully and keep this information for future use.

This fitting guide is intended for the eyecare practitioner, but should be made available to the patient upon request. The eyecare practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

# eyedia® soft55 (METHAFILCON A)
# DAILY WEAR SOFT CONTACT LENS

***CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACITIONER***

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## INTRODUCTION:

This Professional Fitting Guide has been developed to provide practitioners with information covering characteristics of the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** and to illustrate fitting procedures. Please read carefully and keep this information for future use.

The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is made from Methafilcon A with a water content of 55.0% by weight.

For a complete listing of available lens parameters, please refer to LENS PARAMETERS AVAILABLE.

## PRODUCT DESCRIPTION:

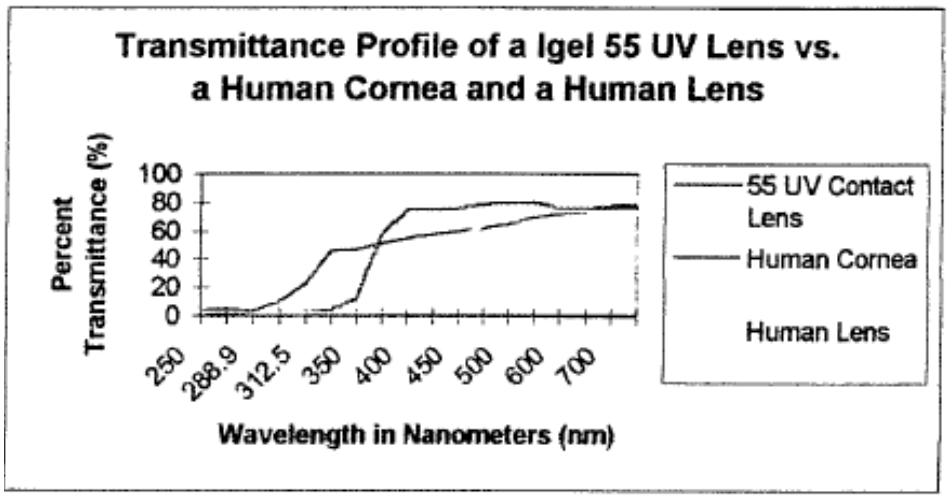
The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is available as a single vision lens. The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). The lens polymer contains an UV absorbing compound. The lenses are tinted using the color additive Reactive Blue #19.

The physical/optical properties of the lens as are:

- Refractive Index : 1.42
- Visible Light Transmittance : 90.3% (Approximately)
- UV Transmittance : <10%
- Surface Character : hydrophilic
- Water Content : 55%
- Specific Gravity : 1.06
- Oxygen Permeability (Dk)* : $18.9 \times 10^{-11}$ ($cm^2$/sec)(ml $O_2$/ml x mm Hg) at 35ºC
  *[revised Fatt Method for determination of oxygen permeability]

**WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.**

The following graph compares the UV transmittance curve of **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** (-6.50 D) to that of human cornea of a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig 2-21, and that of the human crystalline lens from a 25 year old, as described in Waxier, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986,




p.19, fig 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 your eye care practitioner for more information.**

## LENS PARAMETERS AVAILABLE:

The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is a hemispherical shell which cover the cornea and a portion of the adjacent sclera with the following dimensions:

- Chord Diameter : 14.0mm to 15.0mm
- Center Thickness : 0.06mm to 0.40mm
- Base Curve : 8.40mm to 9.30mm
- Powers : -20.00 Diopters to +20.00Diopters

## ACTIONS:

In its hydrated state, the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens**, when placed on the cornea, act as refracting media to focus light rays on the retina when viewing reading material at the reading distance.

## INDICATIONS:

The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The lens may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement (see WARNING SCHEDULE). When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

## CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS SECTIONS:

See package insert for "Contraindications (Reasons Not to Use)", "Warnings", "Precautions" and "Adverse Reactions".

## SELECTION OF PATIENT:

The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is indicated for the correction of myopia and hyperopia in aphakic or not aphakic patients with non-diseased eyes who exhibit no more than 2.00 Diopters of astigmatism and can obtain satisfactory visual acuity, in a power range of +20.00 to -20.00 diopters.

Persons who require only visual correction and who would not or could not adhere to a recommended care regimen of the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and wearing 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. It is also necessary to discuss the information contained in the Patient Instruction / Wearer's Guide with the patient at the time of the initial examination.

Patients selected to wear **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** should be chosen for their motivation to wear contact lenses, general health and cooperation. The eyecare practitioner must take care in selecting, examining and instructing patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part time) and desired lens usage (reading, recreation or hobbies).

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.

## FITTING PROCEDURE for the eyedia® soft55 (METHAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS

a) Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear as described in the Package Insert.
b) Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
c) Place lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variation in the tonicity, pH or the lens solutions and individual tear composition may cause slight changes in fitting characteristics.
d) If the initial lens selection covers the patient's cornea fully, provides discernible movement (0.10mm to 0.30mm) after blink, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed. (see ***Criteria for a Well-fitted Lens*** for **CLINICAL ASSESSMEN**T)
e) Full coverage of the cornea is defined as the lens edge extending beyond the limbal area in all directions. Initial lens evaluation must be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.
f) Following a blink, the lens should move vertically on the patient's eye about 0.10mm to 0.30mm. Using a slit lamp, this movement can be estimated by comparing it with the one millimeter lens peripheral bevel width.
g) When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and Patient Instruction / Wearer's Guide.

### 1. Pre-Fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for daily wear 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.

### 2. Follow-Up care

a. Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.
b. Prior to a follow-up examination, the contact lenses should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
c. With lenses in place on the eyes, evaluate the fitting performance to assure the criteria of a well-fitted lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
d. After the lens removal, conduct a thorough bio-microscopy examination.
    1. Follow-up examinations are recommended by the eyecare practitioner, they are necessary to ensure continued successful contact lens wear.

2. Prior to a follow up examination, the contact lens should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
3. With lenses in place on the eyes, evaluate the fitting performance to assure the criteria of a well-fitted lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
4. After the lens removal, conduct a thorough bio-microscopy examination.
    i. The presence of vertical cornea striate in the posterior central cornea and/or cornea neovascularization is indicative of excessive corneal edema.
    ii. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens.
    iii. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are considered as abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to its optimal conditions. If the **Criteria of a Well-Fitted Lens** is not satisfied during any follow-up examinations, the patient should be refitted with a more appropriate lens.

**3. Fitting Summary:**

- Fitting performance and visual response should be confirmed with the prescription lenses prior to dispensing and the management of certain adaptive symptoms should be discussed with the patient prior to dispensing.
- It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing and slight eye redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these mild symptoms will disappear. If these symptoms persist, the patient should be instructed to contact their eyecare practitioner.

**IN OFFICE CARE OF TRIAL LENSES:**

Eyecare practitioners should educate contact lens technicians concerning proper care of trial lenses.

For **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens,**

- Each contact lens is shipped sterile in sealed blister packs containing the sterile buffered normal saline solution and labeled to the parameters of the lens contained. Hands should be thoroughly washed and rinsed dried with a lint free towel prior to handling a lens. In order to insure sterility, the sterile pack should not be opened until immediately prior to use. To open the blister pack pull back the lid where indicated. Upon removing the cover the lens may be removed and is ready for use.
- **LENS HANDLING (in-office cleaning, disinfecting and storage):**

Trial lenses should be cleaned, rinsed, and disinfected after each use following recommended care instructions with any of the chemical or hydrogen peroxide lens care system approved for use with soft contact lenses. Storage of trial lenses which have been reconditioned should be subject to re-disinfection procedures on a periodic basis; at least weekly.

## RECOMMENDED INITIAL WEARING SCHEDULE:

Although many practitioners have developed their won initial wearing schedules, the following sequence is recommended as a guideline, patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

**THE EYECARE PRACTITIONER SHOULD DETERMINE THE WEARING AND REPLACEMENT SCHEDULES**. Patients tend to over wear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is indicated for daily wear. **THE MAXIMUM SUGGESTED WEARING TIME FOR THE LENSES IS**:

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| DAY | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 and after |
| HOURS | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | All waking hours |

**STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE eyedia® soft55 (METHAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS IS SAFE TO WEAR DURING SLEEP.**

## CLINICAL ASSESSMENT:

1. Criteria of a Well-Fitted Lens

   - to 1.0mm movement in primary gaze
   - to 1.5mm movement in upgaze
   - centration in primary gaze

2. Characteristics of a Tight Lens

   - <0.5mm movement in primary or upgaze

3. Characteristics of a Loose Lens

   - >1.0mm movement in primary gaze
   - >1.5mm movement in upgaze
   - poor centration in primary and upgaze

## MONOVISION FITTING GUIDELINES

1. Patient Selection

   A. Monovision Needs Assessment

   For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient with significant astigmatism (greater than one diopter) in one eye may not be a good candidate for monovision with **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) 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. Monovision contact lens wear may not be optimal for such activities as:

   1) Visual demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
   2) Driving automobiles (e.g. driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised not to drive with this correction, OR may require that additional over-correction be prescribed.

   B. 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, 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 gaze that monovision contact lenses provide.

2. Eye Selection

   Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

   A. 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 bet with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit more hyperopic (less myopic) eye for distance and more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's 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 near lens on the left eye.

3. 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 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 lens. A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left corrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optima 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.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in this guide.

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 t this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. The have the patient look at familiar near objects such as a watch face of 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 is 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.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last 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 lenses in a comfortable familiar environment such as in the home.

Some patients feel automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that patient be passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), 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.

7. Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the instructions 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 spectacles 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 a monovision correction.
- Make sure of proper illumination when carrying out visual tasks.

Success in fitting monovision 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 gaze with monovision.
- The decision to fit a patient with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.
- All patients should be supplied with a copy of the Patient Instruction / Wearer's Guide for **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens**.

## FREQUENT REPLACEMENT PROGRAM:

The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** frequent replacement schedule is prescribed by the eyecare practitioner. At the end of each day, each lens is to be removed, cleaned, and disinfected in the recommended manner prior to re-insertion. Clean and fresh lenses are more comfortable, and are less likely to irritate gentle tissues around the eyes. The eyecare practitioner will recommend an appropriate lens replacement schedule for each patient. He or she will design he schedule for the patient. It is imperative that the patient follow the direction of the eyecare provider.

## PATIENT LENS CARE DIRECTIONS:

Eyecare 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:** First Clean and Rinse, Then Disinfect Lenses

**Basic Instructions:**

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **FRESH, UNEXPIRED** lens care solutions. Never re-use solution.
- Use the recommended system of lens care, either chemical (not heat), or oxidation (hydrogen peroxide) and carefully follow instructions on solution labeling.

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING**.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- 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 eyecare practitioner) and disinfect** lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfecting.
- The eyecare practitioner should recommend a care system that is appropriate for the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

**Note**: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, **disinfect** lenses using the system recommended by the manufacturer and/ or the eyecare practitioner.
- To store lenses, disinfect and leave them in the closed/ unopened case until ready to wear. Lenses stored longer than 12 hours may require cleaning, rinsing and disinfecting again before use. The patient should consult the Package Insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh disinfecting/ storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- **DO NOT HEAT THE DISINFECTING SOLUTION AND LENSES**.

**Lens Deposits and Use of Enzymatic Cleaning Procedure:**

The eyecare practitioner may recommend enzyme cleaning. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners.

Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

**Chemical (Not Heat) Disinfection:**

**Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or neutralizing solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, **disinfect** lenses using the system recommended by the manufacturer and/or the eyecare practitioner.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with fresh saline or neutralizing solution before inserting and wearing, or follow the instructions on the hydrogen peroxide system labeling.
- **DO NOT HEAT THE HYDROGEN PEROXIDE SOLUTION AND LENSES.**
- Leave the lenses in the unopened storage case until ready to put on the eyes.

**Caution**: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

**Care for a Dried Out (Dehydrated) Dry Lens:**

If the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is off the eye and exposed to air for twenty minutes or longer, they will become dry and brittle. To rewet:

- Place the lens in its storage case and soak the lens in recommended rinsing and storage solution for at least one hour or until the lens again feels soft and pliable.
- Clean, rinse and disinfect the rewetted lens using the lens care system recommended by the eyecare practitioner.
- If after soaking, the lens does not become soft or the surface remains dry, **DO NOT PLACE THE LENS IN THE EYE**. Contact the eyecare practitioner.

**Care for a Sticking (Nonmoving) Lens:**

If the lens sticks (stops moving), the patient should be instructed to apply 1 to 2 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 5 minutes, the patient should **IMMEDIATELY** consult the eyecare practitioner.

## Lens Case Cleaning and Maintenance:

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

## Lubricating/ Rewetting Lenses On-Eye:

Eyecare practitioners may recommend a lubricating/re-wetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Disposable and lenses prescribed in a frequent replacement program should be thrown away after the recommended wearing period prescribed by the eyecare practitioners.

## Recommended Lens Care Products:

The eyecare practitioner should recommend a care system that is appropriate for the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens**. Each lens care product contains specific instructions for use and important safety information, which should be read and carefully followed.

## EMERGENCIES:

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

**FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

## REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** should be reported to:

**Clearlab US Inc.**
4200 Jenkins Court, Suwanee,
GA 30024, United States of America
Tel: +1 770 2710211
Fax: +1 770 2710225
Email: USRA@clearlab.com
Website: www.clearlabus.com

## HOW SUPPLIED:

Each lens is supplied sterile in blister packs containing a buffered saline solution. The blister pack and outer box are labeled with the base curve, diopter power(s), diameter, tint, lot number and expiration date of the product.

## SYMBOLS KEY:

The following symbols may appear on the label or carton.

| SYMBOL | DESCRIPTION |
|---|---|
| STERILE | Sterile Using Steam |
| **LOT** | Product Lot Number |
| **EXP** | Expiry Date |
| **BC** | Lens Base Curve |
| **DIA** | Lens Diameter |
| ℞ Only | Caution: Federal law restricts this device to sale by or on the order of a licensed Eye Care Practitioner. |
| ⚠**SINGLE PATIENT USE** | Caution: This is a single patient use device; See Package Insert or Instructions For Use. |
| UV BLOCKING | Lens contains UV blocking properties |

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

clearlab

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