

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.

**clearcolor55™ (Methafilcon A) Spherical
COLOR SOFT CONTACT LENS FOR DAILY WEAR**

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

미광콘택트렌즈®
MI GWANG CONTACT LENS CO., LTD.

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INTRODUCTION

The **clearcolor55™ (Methafilcon A) Color Soft Contact Lens** is made from Methafilcon A with a water content of 55%. This Professional Fitting Guide has been developed to provide practitioners with information covering characteristics of **the clearcolor55™ (Methafilcon A) Color Soft Contact Lens** to illustrate fitting procedures.

PRODUCT DESCRIPTION

The **clearcolor55™ (Methafilcon A) Color Soft Contact Lens** is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate, containing 55% water content. The **clearcolor55™ (Methafilcon A) Color Soft Contact Lens** is tinted with one or a combination of one or more of the following pigments, 'listed' color additives: Reactive black 5, C.I. Vat orange 5, D&C Yellow No. 10, D&C Green No. 6, Phthalocyaninato(2-) copper, Carbazole violet and Titanium dioxide. Lenses that contain a unique tinting pattern are subsequently processed to incorporate the 'listed' color additives, and contain only the amount of color additive needed to accomplish the intended cosmetic effect.

DESIGN: The **clearcolor55™ (Methafilcon A) Color Soft Contact Lens** is available as a single vision lens. It is a hemispherical flexible shell which covers the cornea and a portion of the adjacent sclera.

Chord Diameter:	10.5 mm to 15.5 mm
Center Thickness:	0.090 mm to 0.229 mm
Base Curve:	8.0 mm to 9.8 mm
Powers	-13.00 Diopters to +6.00 Diopters

The physical/optical properties of the lens are:

Refractive Index	1.42 (hydrated)
Light Transmission (tinted)	greater than 90%
Water Content	55%
Oxygen Permeability	21.12×10^{-11} (cm ² /sec) (ml O ₂ /ml × mm Hg @ 35°C), (revised Fatt method).

INTENDED USE

The **clearcolor55™ (Methafilcon A) Color Soft Contact Lens** is intended for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The lenses may be disinfected using a chemical or hydrogen peroxide disinfection system. Eyecare practitioners may prescribe for lenses for daily wear and/or frequent replacement.

When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.

ACTIONS

In its hydrated state, the **clearcolor55™ (Methafilcon A) Color Soft Contact Lens**, when placed on the cornea, acts as a corrective refracting medium to focus light rays on the retina.

PATIENT SELECTION

- **clearcolor55™ (Methafilcon A) Color Soft Contact Lens** is intended for patients that requires optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 2.00D or less of astigmatism.
- The lenses are also intended for patients, whom have undergone treatment of acute or chronic ocular pathologies such as, bullous keratopathy, corneal erosions, entropion, corneal edema, and corneal dystrophies as well as post surgical conditions resulting from cataract extraction an corneal surgery, to be used as a therapeutic bandage to relieve corneal pain, at the sole discretion and under direct supervision of a qualified and licensed eyecare professional.
- With the cosmetic effects, such as tints, under the sole discretion and direct supervision of a qualified eyecare professional, the lenses are also intended for use as prosthetic devices for sighted and non-sighted eyes, with or without lens power.
- Persons who require only visual correction and who would not or could not adhere to a recommended care regimen of the **clearcolor55™ (Methafilcon A) Color Soft 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 **clearcolor55™ (Methafilcon A) Color Soft 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 **clearcolor55™ (Methafilcon A) Color Soft Contact Lens**

1. 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.

2. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
3. Place 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.
4. 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 ASSESSMENT**).
5. 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.
6. 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.
7. 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.

IN OFFICE CARE OF TRIAL LENSES

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.

WEARING SCHEDULE

The wearing schedule should be determined by the prescribing eyecare practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. Patients should be given a wearing schedule and carefully instructed on the handling and care of their lenses as discussed in the Package Insert. Also be sure to complete the personal wearing/replacement schedule record in the Patient Instruction/ Wearer's Guide. The lens must be removed, cleaned, disinfected or disposed of and replaced with a new lens as determined by the prescribing eyecare practitioner. (See the factors discussed in the WARNINGS section.)

Follow-up examinations are necessary to ensure continued successful contact lens wear and to ascertain the effects of the lenses on the eyes. The following schedule is a suggested guideline for daily wear contact lenses:

- 24 hours post-dispensing
- 7 days
- 1 month
- 3 months
- Every 6 months thereafter

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

FREQUENT REPLACEMENT PROGRAM

The **clearcolor55™ (Methafilcon A) Color Soft 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 the schedule for the patient. It is imperative that the patient follow the direction of the eyecare provider.

LENS CARE DIRECTIONS

Eyecare practitioners 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 the instructions on solution labeling.
- Different solutions cannot always be used together and not all solutions are safe for use with all lens. 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 and disinfect** lenses according to the schedule prescribed by the eyecare practitioner. The use of enzyme or any cleaning solution does not substitute for disinfecting.
- The eyecare practitioner should recommend a care system that is appropriate for the **clearcolor55™ (Methafilcon A) Color Soft 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.

Chemical Disinfecting Method

- **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 lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, **disinfect** lens 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 storing lenses.
- After removing the lenses from the lens case, empty and rinse the 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.
- **DO NOT HEAT THE DISINFECTING SOLUTION AND LENSES.**

Hydrogen Peroxide Disinfecting Method

- **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 lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, **disinfect** lens using the system recommended by the manufacturer and/ or the eyecare practitioner.
- When using hydrogen peroxide lens care system, 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.

PROFESSIONAL FITTING GUIDE



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.

Precaution: Use only a chemical (not heat) lens care system. Use of heat (thermal) care system can discolor the lenses.

LUBRICATING / RE-WETTING 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.

CARE FOR NON-MOVING LENS

If the lens stops moving or cannot be moved, the patient should be instructed to apply 1 - 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.

RECOMMENDED LENS CARE PRODUCTS

The eyecare practitioner should recommend a care system that is appropriate for the **clearcolor55™ (Methafilcon A) Color Soft 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 **clearcolor55™ (Methafilcon A) Color Soft Contact Lens** should be reported to the address below.

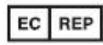
Additional Package Insert and Patient Instruction/ Wearer's Guide are available from:

PROFESSIONAL FITTING GUIDE

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HOW SUPPLIED

Each lens is supplied sterile in a sealed blister pack or glass vial containing buffered normal saline solution. The blister pack or glass vial is labeled with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens.

Note: **Do not use if blister is damaged or seal is broken.**

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