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

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

clearcolor™ (POLYMACON) 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.

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MATERIAL CHARACTERISTICS

The **clearcolor™ (polymacon) Color Soft Contact Lens** is a nonionic lens material, (polymacon) which is a hydrophilic polymer of 2-Hydroxyethyl methacrylate (2-HEMA). The co-polymer consists of 62% polymacon and 38% water by weight when immersed in normal buffered saline solution. Lenses are tinted with one or a combination of one or more of the following pigments, 'listed' color additives: D&C Yellow No. 10, D&C Green No. 6, D&C Red No. 17, 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.

DESCRIPTION OF LENS

The **clearcolor™ (polymacon) Color Soft Contact Lens** is hemispherical shells with molded spherical base curves and lathe-cut front surfaces. The **clearcolor™ (polymacon) Color Soft Contact Lens** is fabricated from a nonionic polymer.

The nonionic lens material, (polymacon) is a hydrophilic polymer of 2-Hydroxyethyl methacrylate (2-HEMA). The copolymer consists of 62% polymacon and 38% water by weight when immersed in normal buffered saline solution. Lenses are tinted with one or a combination of one or more of the following pigments, 'listed' color additives: D&C Yellow No. 10, D&C Green No. 6, D&C Red No. 17, 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.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent or colored optical surface. The (polymacon) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it is maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

Chord Diameter:	12.8 mm to 14.8 mm
Center Thickness:	0.03 mm to 0.30 mm
Base Curve:	8.0 mm to 9.5 mm
Spherical Powers (spherical lens)	0.00 Diopters to +25.00 Diopters
	0.00 Diopters to -25.00 Diopters

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 38% water by weight. The physical properties of the lens are:

Refractive Index	1.438 (hydrated)
Light Transmission (tinted)	greater than 88%
Water Content	38%
Oxygen Permeability	8.95×10^{-11} (crn^2/sec) (ml O_2/ml × rnm Hg @ 35^oC), (revised Fatt method).

ACTIONS

In its hydrated state, the **clearcolor™ (polymacon) Color Soft Contact Lens**, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

INDICATIONS

The **clearcolor™ (polymacon) Color Soft Contact Lens** for daily wear are indicated for the correction of visual acuity (except plano lens) in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Eye care practitioners may prescribe the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

CAUTION

Due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner 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 must 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 practitioner.

WARNINGS

Please reference Warning in the Package Insert included at the end of this Fitting Guide.

PRECAUTIONS

Please reference Precautions in the Package Insert included at the end of this Fitting Guide.

ADVERSE REACTIONS

Please reference Adverse Reactions in the Package Insert Included at the end of this Fitting Guide.

PATIENT SELECTION

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of the **clearcolor™ (polymacon) Color Soft Contact Lens** should not be provided with this lens. All necessary steps in lens care and all precautions and warnings should be discussed and understood by the patient (*Review Package Insert with patient*).

Fitting procedure for the clearcolor (spherical)

FITTING PROCEDURE

1. Pre-fitting Examination
2. Initial lens power selection
3. Initial lens diameter and base curve selection
4. Initial lens evaluation
5. Follow-up care

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 lens(refer to contraindications)
- Collect and record baseline clinical information to which post-fitting examination results can be compared
- Make ocular measurements for initial contact lens parameter selection

2. Initial Lens Power Selection

a) Convert the spectacle Rx to minus cylinder forms
b) Compensate the spectacle Rx for vertex distance is the power is greater then + or - 4.00 diopters

c) Drop the cylinder
d) Add + 0.25 diopter to compensate for minus tear lens
e) If refractive astigmatism exceeds 0.75diopter, determine equivalent sphere and then compensate for power by adding +0.25 diopter for minus tear lens

3. Initial Lens Diameter and Base Curve Selection

The lens is currently offered in one diameter (14.00mm) and one base curve (8.6mm)

4. Initial Lens Evaluation

a) Check Lens Centration, Movement, and Size

The criteria for a well fit lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.5 millimeters, lags downward about 1 to 2 millimeters on upward gaze, and does not move excessively as a result of blinking or exaggerated eye movements.

After the trial lens settled on the eye (5 - 10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with the slightest pressure and return to the centered position when released.

Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1 - 2 millimeters.

b) Refract Over the Lens and Determine Visual Acuity

Allow approximately 10 minutes for fluid equilibration and patient adaptation prior to over refracting. Determine best visual acuity when final over refraction has been achieved. If good visual acuity cannot be obtained through the lens with spherocylindrical over refraction, re-evaluation of the physical fit should be considered. Trial lens procedure should be repeated with lenses of different base curves.

c) Determine the Optical Power for the Lens Selected

When the proper physical fit has been determined, convert the over refraction through the diagnostic lens to equivalent sphere and add this to the power of the trail lens. This will provide the final power of the lens.

5. 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 fitting performance to assure that **CRITERIA OF A WELL FITTED LENS** continues to be satisfied. Examine the lenses closely for surface deposition and/or damage.
d) After the lens removal, conduct a thorough biomicroscopy examination.

1. The presence of vertical corneal striae in the posterior central cornea and/or cornea neovascularization is indicative of excessive corneal edema.
2. The presence of corneal staining and/or lirnbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the **CRITERIA OF A WELL FITTED LENS** is not satisfied during any follow-up examinations, the patient should be re-fitted with a more appropriate lens.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **clearcolor™ (polymacon) Color Soft Contact Lens** when any of the following conditions are present:

- Acute and 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 lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the **clearcolor™ (polymacon) Color Soft Contact Lens.**
- Any active corneal infection (bacterial, fungi, or viral)
- If eyes become red or irritated.
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.

FOLLOW-UP EXAMINATIONS:

- Within one week of lens dispensing
- After three weeks of lens wear
- After seven weeks of lens wear
- After each six month period of lens wear.

At the follow-up examinations, the patient should report good subjective quality of vision. Adaptation to vision with **clearcolor™ (polymacon) Color Soft Contact Lens** should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the practitioner should:

1. Check distance and near acuity with lens in place.
2. Over-refract to verify lens prescription.
3. Observe the position of the lens on the cornea. The lens should be centered and move on upward gaze and with a blink.
4. Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
5. Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
6. Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates, and perilimbal injection. Reinsert the lens only after all residual Fluorescein has dissipated from the eye.
7. Clean the lens with a prophylactic surfactant cleaner, and examine for deposits, foreign bodies or physical imperfections of the lens surface.

LENS HANDLING (in-office cleaning, disinfecting and storage)

Wash and rinse hands thoroughly, making certain all soap residues have been rinsed away before drying with a lint-free towel. *It is suggested to wet the lens while in the eye using wetting drops before removal.* Always start with the right lens first in order to avoid mixing the lens. In removing the lens, try to avoid touching the inside (concave) surface of the lens. It is possible, though not likely, that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out. After removing the lens from its container assure that it is clean, clear and wet.

Each **clearcolor™ (polymacon) Color Soft Contact Lens** received in the eye care practitioner's office is received sterile in a sealed blister pack with sterile buffered normal saline solution and labeled as to the parameters of the lens contained. To assure sterility, the blister pack should not be opened until ready for use.
To open the blister pack, pull back on the top where indicated. Upon removing the top cover of the blister pack, the lens may be removed and is ready for use.
Prior to reusing in a diagnostic procedure or before dispensing to a patient, the lens should be surfaced cleaned and disinfected.

CLEANING

A surfactant cleaner must be used with the **clearcolor™ (polymacon) Color Soft Contact Lens** to ensure a clean lens surface. A single procedure is as follows:

Apply 3 to 4 drops to the lens, and then rub the surfaces of the lens against the palm of one hand with the index finger of the other hand or between the thumb and the forefinger for twenty seconds.

RINSING

Thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution.

CHEMICAL (NOT-HEAT) LENS CARE SYSTEM

A sterile rinsing, storing and disinfecting multipurpose solution should be used to rinse and chemically disinfect **clearcolor™ (polymacon) Color Soft Contact Lens**. After cleaning the lens, rinse with a liberal amount of fresh multipurpose solution to remove loosened debris and traces of cleaner. The lens should then be placed in the plastic container supplied in a multi-purpose solution kit and filled with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfecting, the lens must remain in the disinfecting solution for the recommended period of time as written on the multipurpose solution bottle. Before reinsertion, lens should be rinsed with fresh sterile rinsing solution.

LENS CARE DIRECTIONS

Please reference LENS CARE DIRECTIONS in the Package Insert included at the end of this Professional Fitting Guide.

STORAGE

The **clearcolor™ (polymacon) Color Soft Contact Lens** must be stored in the recommended solutions. If exposed to the air, the lens will dehydrate. If a lens dehydrates, it should be soaked ONLY in a soft contact lens storage solution until it returns to a soft, supple state. It should not be put on an eye until it has been put through a complete disinfection cycle.

RECOMMENDED WEARING SCHEDULE

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lens.

Patients tend to overwear the lens initially. It is important not to exceed the initial wearing schedule. Regular check-ups, as determined by the eye care practitioner, are also extremely important. The maximum suggested wearing schedule for the **clearcolor™ (polymacon) Color Soft Contact Lens** is reflected below.

DAY	HOURS
1	6
2	8
3	10
4	12
5	14
6	All Waking hours*

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE clearcolor™ (POLYMACON) COLOR SOFT CONTACT LENS IS SAFE TO WEAR DURING SLEEP.

FREQUENT/PLANNED REPLACEMENT

Clearlab SG Pte. Ltd. Recommends that the **clearcolor™ (polymacon) Color Soft Contact Lens** be discarded and replaced with a new lens every two months. However, as the eye care practitioner, you are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

RECOMMENDED LENS CARE PRODUCTS

The eye care practitioner should recommend a care system that is appropriate for the **clearcolor™ (polymacon) Color Soft Contact Lens**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

EMERGENCIES

The patient should be informed that if chemicals 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 THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS

Practitioners should report any adverse reactions to **clearcolor™ (polymacon) Color Soft Contact Lens** within 5 days to Clearlab SG Pte. Ltd.. Additional Package Inserts and Patient Instruction/ Wearer's Guides are available from:

Clearlab SG Pte. Ltd.
139 Joo Seng Road,
Singapore 368362
Tel: +65 6749 1090
Fax: +65 6282 3953
Email: Regulatory@clearlab.com
Website: www.clearlab.com

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.

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