

BioColors

Soft (hydrophilic) Color Enhanced Contact Lens

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION

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IMPORTANT: Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner but should be made available to the patient upon request.

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DESCRIPTION OF DEVICE:

Orion Vision Group BioColors Soft (Hydrophilic) contact lens(es) are color enhanced soft contact lenses that have been previously prescribed for a specific patient by a licensed professional. They have been supplied to Orion Vision Group to be modified by a stamping process, using color additives that have been listed as safe for contact lenses in accordance with the FDA's color additive regulations. The color additives are used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect. As part of the manufacturing process, the lenses containing the color additives are thoroughly (washed, purged, cleaned) to remove unbound reactive color additives. The manufacturing process alters and/or changes the specifications to the clear version of a contact lens by affixing a listed color reactive additive on that portion of the anterior (front) surface of the lens that corresponds to the iris.

The color additive effect is formed by reacting one or more color additives listed with (poly hydroxyethyl methacrylate). The color additive titanium dioxide is incorporated into the monomer during the polymerization with the help of a coupling agent and is printed on that portion of the anterior (front) surface of the lens that corresponds to the iris. The manufacturing process then affixes the 'listed' color reactive additive over the iris creating an opaque pattern by affixing the titanium dioxide. Color additives listed are Titanium Dioxide (21 CFR 7.3126) Iron Oxide (Red, Yellow and Black; 21 CFR 73.3125) Chromium Green (21 CFR.3111) Phthalocyanine Green (21 CFR 73.3124) Carbazole Violet (21 CFR 73.3045) Phthalocyanine Blue (21 CFR 74.3045) The color additives listed above may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended prosthetic effect. The color additives used are not removed by lens handling, cleaning, or disinfecting when properly cared for.

Measured Visible Light: The optic zone remains clear (un-tinted) unless specified for patient requirements. The clear optic zone provides light transmission greater than the required 70%.

The BioColors Soft (Hydrophilic) contact lens(es) is available as a single vision lens. The hemispherical flexible shell which covers the cornea and a portion of the adjacent sclera. The lens material is offered in Methafilicon 55%, and Polymacon 38%. Orion Vision Group is not the manufacturer of the clear lens and is therefore exempt from any information only a manufacturer could provide. Product inserts are available on request and are also available on the website.

Orion Vision Group BioColors Available Colors:

Black, White, Stormy Gray, Granite, Dark Chocolate, Pecan, Chestnut, Honey, Orange, Caribbean, Baby Blue, Lavender, Evergreen, Turquoise, Blue/Gray, Aqua Enhancer, Blue Enhancer, Green Enhancer, Red, Yellow, and Brilliant Blue

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BioColors Iris patterns are offered in 2 Patterns, the X-Series and the V-Series.

MATERIAL DESCRIPTION:

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extends slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be 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.

The non-ionic lens material, **Polymacon** is an ultra-high molecular weight homo-polymer of 2-hydroxyethyl methacrylate (2-HEMA) crossed linked with ethylene glycol dimethacrylate. It consists of 62% Polymacon and 38% water by weight when immersed in normal buffered saline solution. Lenses are available in clear and with a blue visibility handling tint, phthalocyanato (-2) copper.

The non-ionic lens material, **Methafilcon A**, is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and Methacrylic Acid, cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 45% methafilcon A and 55% water by weight when immersed in normal buffered saline solution. Lenses are available in clear and with a blue visibility handling tint, phthalocyanine blue. Methafilcon A (UV) contains BHPEA UV absorber. The UV-Absorber is included during the manufacturing process as a monomer.

	Polymacon	Methafilcon A
Refractive Index	1.44 (Hydrated)	1.415 (Hydrated)
Light Transmission (clear & tinted)	>95%	>95%
Water Content	38%	55%
Specific Gravity (Hydrated)	1.17	1.099
Oxygen Permeability	9 X 10 ⁻¹¹ (cm ² / sec) (ml O ₂ /ml x mm Hg @ 35oC), (revised Fatt method)	18 X 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35oC), (revised Fatt method)

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The available parameters for the **Color Enhanced Soft Contact Lenses** are as follows:

Parameter	Range	Tolerance
Base Curve	7.8mm to 9.2mm	± 0.2mm
Diameter	13.5mm to 16.00mm	± 0.2mm
Clear Pupil Sizes - 2.8, 3.3, 4.2, 5.0, 6.0, (5.0 standard)	NA	NA
Black Pupil Sizes – 3.0, 3.5, 4.0, 4.5, 5.0, 6.0, (5.0 standard)		
Power	Varies by patient prescription	NA
Cosmetic Feature Options		
Starburst	Limbal Ring	Starburst and Limbal Ring

INDICATIONS FOR USE:

The BioColors Soft Contact Lens is indicated for daily wear to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for occlusive therapy for conditions such as diplopia, amblyopia, aniridia, or extreme photophobia.

The BioColors Soft Contact Lens is indicated for daily wear for correction of refractive ametropia (myopia and hyperopia) in aphakic or non aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 1.00 diopter (Sphere) or 4.00 diopter (Toric) that does not interfere with visual acuity.

The BioColors Soft Contact Lens provides ease of patient handling and can alter the appearance of the natural iris color. The eye care practitioner may prescribe the contact lens for frequent replacement wear, with cleaning, rinsing and disinfection and scheduled replacements as prescribed by the eyecare professional. The lens may be disinfected using the Lens Fresh disinfection system only, hydrogen peroxide systems containing less than 3% hydrogen peroxide or a non-heat disinfection system.

SPECIAL PRECAUTIONS FOR THE EYE CARE PRACTITIONER:

Lens is immersed in BioTrue® Multi-Purpose Solution (or equivalent) containing sodium citrate, sodium chloride, boric acid, sorbitol, AMP-95, Tetronic 1304, edetate disodium 0.05%, Polyquad® (Polyquaternium-1) 0.001% and Aldox® (myristamidopropyl dimethylamine) 0.005% as preservatives. If the patient is allergic to edetate disodium or POLYQUAD® (polyquaternium-1) preservatives, the lens should be rinsed with fresh, sterile rinsing solution, cleaned with a surfactant cleaner and placed in another

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prescribed disinfecting solution. Follow the manufacturer's instructions on the disinfection solution label.

Caution: Non-sterile. Dispense to patient within 30 days of processing date. Clean and disinfect prior to insertion with an appropriate solution according to the manufacturer's instruction.

- If continual storage of the contact lens is preferred, the lens should be cleaned and disinfected every 30 days from processing date. Clean and disinfect prior to insertion with an appropriate solution according to the manufacturer's instruction.
- Patients may experience a reduction in visibility while wearing a dark shade of tint on the lenses in conditions of low illumination.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE THE BioColors Soft Contact Lens when any of these conditions are present:

- Acute and sub-acute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Excessive watering (tearing) of the eye.
- Unusual eye secretions.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobias).
- Dry eyes or redness of the eye.

If any of the above exists, instruct patients to **IMMEDIATELY REMOVE LENSES**.

ADVERSE REACTIONS:

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain.
- Comfort is less than when lens was first placed on eye.
- Feeling that something is in the eye such as a foreign body or scratched area.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.

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- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for BioColors Soft Contact Lens.
- Any active corneal infection (bacterial, fungi or viral).

If discomfort or problem exists, remove the lens, and examine it. If the lens is damaged, **DO NOT PUT THE LENS BACK INTO THE EYE**. Place the lens in the storage case and contact the eye practitioner. If the lens has dirt, an eyelash, or other foreign body on it or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENS AND CONSULT THEIR EYE CARE PRACTITIONER**. When any of the above problems occur, a serious condition such as infection, corneal ulcer neovascularization or iritis may be present. Instruct the patient to **KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.

WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **LOSS OF VISION**; therefore, if you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, **IMMEDIATELY REMOVE YOUR LENSES and PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**

- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers.
- Do not reuse or "top off" solution which is the addition of fresh solution to old solution that has been sitting in the case. This reduces the effective lens disinfection and could lead to severe infection, vision loss, or blindness.

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.

PRECAUTIONS

- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions that are fresh and sterile. Never use solutions recommended for conventional hard contact lenses only.

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- Chemical disinfecting solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfecting.
- **ALWAYS:** Use FRESH, STERILE, UNEXPIRED lens care solutions.
- Follow directions in the package inserts for the use of contact lens solutions. Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- **CAUTION:** Do not use saliva or anything other than the recommended solution for lubricating or wetting lenses.
- Keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage the lenses.
- Follow the lens care directions for care for a dried out (dehydrated) dry lens if the lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on care for sticking lens. The lens should move freely on the eye for the continued health of the eye. If no movement of the lens continues, the patient should be instructed to **IMMEDIATELY** consult his or her eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water base cosmetics are less likely to damage lenses than oil-base.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the practitioner about wearing lenses during sporting activities.
- Inform the health care practitioner about being a contact lens wearer.
- Never use tweezers without silicone tip or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with your fingernails.
- Always contact the eye care practitioner before using any medicine or medications in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that the patient not wear contact lenses.

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- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

WEARING SCHEDULE

WEARING AND REPLACEMENT SCHEDULES ARE DETERMINED BY THE EYE CARE PRACTITIONER. Patients may initially over wear the lenses. Emphasize the importance of adhering to an initial max wearing schedule and regular checkups.

LENS CARE DIRECTIONS

Wash and rinse your hands thoroughly BEFORE HANDLING LENS. Clean one lens first (always the same lens first to avoid mix-ups), rub and 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 lenses using the system recommended by the eye care practitioner. To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the solution package insert and disinfect lenses again prior to usage or consult the eye care practitioner for information on storage of lenses.

Chemical (NOT HEAT) Lens Disinfection (Including Hydrogen Peroxide):

- Wash and rinse your hands thoroughly BEFORE HANDLING LENS.
- Clean and rub the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the eye care regimen recommended by the eye care 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 a fresh solution recommended for rinsing before inserting and wearing or follow the instructions on the disinfection solution labeling.
- Leave the lenses in the unopened storage case until ready to put on the eyes.

NOTE: DO NOT HEAT THE DISINFECTING SOLUTION AND LENSES.

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.

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Lens Care Regimen: Patients must adhere to the lens care regimen recommended by their eye care practitioner for the BioColors Soft Contact Lens for daily wear. Failure to follow this procedure may result in the development of serious ocular infections.

Lens Case Cleaning: Contact lens cases can be a source of bacteria growth. After removing the lens from the case, empty and rinse the lens storage case with solution recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with a new storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

Care for a Dried Out (dehydrated) Dry Lens: If for some reason your lenses dry out completely a minimum of handling is important, as they are very brittle in the dehydrated state. Carefully place them in rinsing or storage solution for a minimum of thirty minutes during which time they will become soft and flexible. Then follow the cleaning, rinsing, and disinfecting procedures – including soaking the lens in storage and disinfecting solution for the recommended time before wearing again.

Care for a sticking (nonmoving) lens: If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 drops of 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 15 minutes, the patient should **IMMEDIATELY** consult the eye care practitioner.

Storage: The BioColors Soft Contact Lens for daily wear must be stored only in the recommended solutions. If exposed to the air, the lenses will dehydrate. If the lens dehydrates, reference above section on caring for dried out (dehydrated) lens.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

Enzyme cleaning may be recommended by the eyecare practitioner as it removes protein deposits on the lens that cannot be removed with regular cleaners. This is important for the wellbeing of the patient's lenses and eyes, because if they are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine daily cleaning and disinfecting. The patient should carefully follow the instructions in the enzymatic cleaning labeling. If enzyme tablets are used, completely dissolve the tablet before immersing or particles can attach to the lens color and cause small, blotchy spots on the color.

STORAGE

Only store the BioColors Soft Contact Lens in the recommended solutions or the lenses will dehydrate from air exposure. If lens dehydrates, reference the original lens manufacturer's package insert for corrective action.

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RECOMMENDED LENS CARE PRODUCTS: The eye care practitioner should recommend a care system that is appropriate for the BioColors Soft Contact Lens for daily wear. 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, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should:





IMMEDIATELY, FLUSH EYES WITH TAP WATER AND CONTACT THE EYE CARE PRACTICIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUTT DELAY.

HOW SUPPLIED:

Each BioColors Soft Contact Lens is supplied non-sterile, in a single screw cap vial immersed in BIO-TRUE® Multipurpose Solution (or equivalent). Follow the manufacturer's instructions on the disinfection solution label.

Dispense to patient within 30 days of processing date. Clean and disinfect prior to insertion with an appropriate solution according to the manufacturer's instruction. For continued storage, the lens should be cleaned and disinfected at least every 30 days from processing date. The attached Orion Vision Group BioColors label contains the processing date, expiration date, lot number, product specifications and order number applicable to the processing of the BioColors contact lens.

Labeling Symbols Definition:

	Lot Number		Consult Instructions for Use
	Expiration Date	PWR (Fv')	Power in diopters
BC (r₀)	Base Curve in millimeters	DIA (ØT)	Diameter in millimeters
	Legal Manufacturer	R_x only	Federal (USA) law restricts the use of this device to sale by or on the order of a physician

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions in patients wearing BioColors Soft Contact Lens should be reported to:



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ORION VISION GROUP

1800 SANDY PLAINS INDUSTRIAL PKWY STE 310

MARIETTA GA 30066 USA.

Tel: (866)300-6257,

Fax: (404)393-6880

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