

# SOFLENS®

(polymacon)  
Contact Lenses

## SYMBOL REFERENCE GUIDE

For labels and cartons:

	Indicates the CE Conformity Marking and the Notified Body Number		Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Fee Paid for Waste Management		Diopter (Lens Power)
	Sterile Using Steam or Dry Heat		Base Curve
	See Instruction Leaflet		Lower Limit of Temperature
	Diameter		Effective Date
	Use by Date (Expiration Date)		
	Batch Code		

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

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## DESCRIPTION

All Bausch + Lomb SOFLENS® (Clear and Visibility Tinted) Contact Lenses are available as Spherical lenses. The lens material (polymacon), is a hydrophilic polymer of 2-hydroxyethyl methacrylate, and is 38.6% water by weight when immersed in saline solution. These lenses are hemispherical flexible shells of the following dimensions:

• Chord Diameter:	12.0mm to 18.0mm
• Center Thickness:	0.02mm to 1.0mm
• Posterior Apical Radius:	5.0mm to 12.0mm
• Powers (Spherical):	See "Indications"

The physical/optical properties of the lens are:

Specific Gravity:	112
Refractive Index:	1.43
Surface Character:	Hydrophilic
Water Content:	38.6%
Oxygen Permeability (Dk):*	UNITS
SOFLENS® Contact Lens (clear)	8.4
SOFLENS® Visibility Tinted Contact Lens	8.5
NaturalTint® Contact Lens Average	9.3
Light Transmittance: C.I.E.**	Y Value
SOFLENS® Contact Lens (Clear)	- approximately 98%
SOFLENS® Visibility Tinted Contact Lens	- approximately 86% to 98%
NaturalTint® Contact Lenses	
Blue	- approximately 82%
Aqua	- approximately 84%
Green	- approximately 76%
Brown	- approximately 62%

\*Dk = units x 10<sup>-11</sup> cm<sup>3</sup> O<sub>2</sub> (STP) x cm / (sec x cm<sub>2</sub> x mm Hg) at 34°C (Polarographic Method)

\*\*CIE light transmittance will differ by average thickness across the optical zone for lenses tinted with Reactive Blue 246.

Bausch + Lomb SOFLENS® (polymacon) Visibility Tinted Contact Lenses (including Occasions™ Multifocal, PA1, Sofspin,™ O3, O4, Optima™ 38 and Optima™ 38/SP) are tinted blue using Reactive Blue 246 or 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone to make the lens more visible for handling purposes. The apparent color of the Bausch + Lomb SOFLENS® (polymacon) Visibility Tinted Contact Lenses may decrease slightly following repeated disinfection. This will not affect the safety or performance of the lens.

NaturalTint® Contact Lenses are tinted with any of, or with combinations of, the following lens colors: blue, green, aqua, brown and yellow. These lenses are tinted with synthetic dyes (Blue) 7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone, (Green) 16,17-Dimethoxydinaphtho[1,2,3-cd:3',2'-1m]perylene-5,10-dione, (Brown) 16,23-Dihydrodinaphtho[2,3-a:2',3'-i], naphtho[2',3':6,7] indolo[2,3-c] carbazole-5,10,15,17,22,24-hexone or (Yellow) N,N-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide) that impart colors to the lens which combine with eye color to produce a natural appearance.

## ACTIONS

In its hydrated state, the Bausch + Lomb SOFLENS® (polymacon) Contact Lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.

## INDICATIONS (USES)

### Daily Wear

The Bausch + Lomb SOFLENS® (polymacon) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes, that exhibit astigmatism of 2.00 diopters or less and can obtain satisfactory visual acuity, in a power range of -20.00 to +20.00 diopters.

Occasions™ Multifocal and PA1 are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic, presbyopic persons with non-diseased eyes, that exhibit astigmatism of 2.00 diopters or less. The bifocal lens is indicated for patients requiring up to 2.00 diopters of refractive add. The lens provides a nominal functional add of 1.50 diopters in a power range of -9.00 to +6.00 for Occasions™ Multifocal, and -6.00 to +6.00 diopters for PA1.

NaturalTint® Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes, that exhibit astigmatism of 2.00 diopters or less and can obtain satisfactory visual acuity, in a power range of -9.00 to +15.00 diopters. These may also be used for color enhancement of the eye and for ocular masking.

Eye care practitioners may prescribe the lenses for traditional or frequent/planned replacement wear, with cleaning disinfection and scheduled replacement (see WEARING SCHEDULE). The lenses may be disinfected using either a heat or chemical disinfection system.

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## Extended Wear

The Bausch + Lomb SOFLENS® (polymacon) O3 and O4 Contact Lenses are indicated for extended wear from 1 to 7 days between removals for cleaning and disinfection or replacement as recommended by the eye care practitioner. The lenses are indicated for the correction of visual acuity of myopic and hyperopic, phakic patients with non-diseased eyes, that exhibit astigmatism of 2.00 diopters or less and can obtain satisfactory visual acuity in a power range of -9.00 to +4.00 diopters.

Eye care practitioners may prescribe the lens for traditional or frequent/planned replacement wear, with cleaning disinfection and scheduled replacement (see WEARING SCHEDULE). The lenses may be disinfected using either a heat or chemical disinfection system.

## CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb SOFLENS® (polymacon) Contact Lens when any of the following conditions exist:

- 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 non-aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses 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 Bausch + Lomb SOFLENS® (polymacon) Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

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## IMPORTANT

This package insert is effective as of revision date on cover and supersedes all prior inserts for the products described below. 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 patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

## CAUTION

Federal (U.S.A.) Law Prohibits Dispensing Without Prescription.

## VISION CORRECTION USE

For all Bausch + Lomb SOFLENS® (polymacon) Contact Lenses (including clear, visibility tinted, cosmetically tinted, daily wear or extended wear polymacon hydrophilic contact lenses).

### SOFLENS includes the following types:

O3, O4, Occasions™ Multifocal, Optima™ 38, Optima™ 38/SP, U3, U4, Sofspin™, HO3, HO4, B3, B4, PA1, F3, H3, H4, N and NaturalTint® Contact Lenses

Spherical Lenses for: Nearsightedness (Myopia), Farsightedness (Hyperopia), Presbyopia, Not-aphakic and/or after Cataract Surgery (Aphakia)

## WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- 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**.
- Daily wear lenses are not indicated for overnight wear, and **patients should be instructed not to wear these lenses while sleeping**. Clinical studies have shown that the risk of serious adverse reactions is increased when contact lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- NaturalTint® Contact Lenses reduce the amount of light entering the eye and should not be used under reduced illumination conditions such as night driving.
- As with all soft bifocal lenses, Occasions™ Multifocal and PA1 Bifocal contact lenses may require a number of fitting procedures before a final lens selection is made. As a patient's add requirement increases, the probability of the patient achieving good visual acuity decreases. A realistic visual expectation for the average patient is that distance VA will be comparable to spectacles; near VA probably slightly less.

## EXTENDED WEAR

- The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient; improper lens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants. While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates, and epithelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.
- The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, practitioners' views of extended wearing times vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing extended wearing periods from 1 to 7 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with a proper care regimen. Some practitioners also recommend frequent replacement of lenses at intervals such as one to two weeks. Other practitioners may prescribe disposable contact lens wear where lenses are disposed of at each removal.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eye care practitioner.

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## Who Should Know That the Patient is Wearing Contact Lenses

- Patients should inform their doctor (health care practitioner) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you do not wear lenses.

## ADVERSE REACTIONS

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

- Eye sting, burn, or itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:

- Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care 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 lenses and consult the eye care practitioner.**

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## PRECAUTIONS

### Precautions for Eye Care Professionals

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care professional 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 should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on eye should be carefully monitored by the prescribing eye care professional.
- Eye care professionals should instruct the patient to **REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with sterile saline solution that is recommended for in-eye use.
- The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care professional.
- Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily wear basis. Patients should be carefully evaluated for extended wear prior to prescription and dispensing, and eye care professionals should conduct early and frequent follow-up examination to determine ocular response to extended wear.
- 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.
- Aphakic patients should not be fitted with Bausch + Lomb SOFLENS® (polymacon) Contact Lenses until the determination is made that the eye has healed completely.

Eye care professionals should carefully instruct patients about the following lens care and safety precautions. It is strongly recommended that patients be provided with a copy of the Bausch + Lomb SOFLENS® (polymacon) Patient Information Booklet available from Bausch + Lomb and understand its contents prior to dispensing the lenses.

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If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should **immediately remove the lens and contact his or her eye care practitioner** or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

### Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

## SELECTION OF PATIENTS

The eye care professional should not fit patients who cannot or will not adhere to a recommended care or replacement regimen, or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and cleaning 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 ensure compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

## Handling Precautions

- 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 products.
- Be sure that before leaving the eye care professional's office, the patient is able to remove lenses promptly or have someone else available to remove them.
- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle lenses carefully and avoid dropping them.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Information Booklet for the Bausch + Lomb SOFLENS® (polymacon) Contact Lenses and those prescribed by the eye care professional.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer's labeled lens care instructions with the patient.

- Always use **fresh unexpired** lens care solutions.
- Always 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.
- Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (stored). Prolonged periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens in the Patient Information Booklet if lens surface does become dried out.
- Do not use saliva or anything other than the recommended solution for lubricating or wetting lenses.
- Tap water, distilled water or homemade saline should not be used as a substitute for any component in the lens care regimen since they have been associated with an *Acanthamoeba* keratitis infection.

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Patients selected to wear Bausch + Lomb SOFLENS® (polymacon) Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care professional must take care in selecting, examining and instructing contact lens 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.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear. If these symptoms persist, the patient should be instructed to contact his or her eye care professional.

## FITTING PROCEDURE

### 1. Pre-Fitting Examination

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

- determine whether a patient is a suitable candidate for contact lenses (consider patient hygiene and mental and physical state),
- make ocular measurements for initial contact lens parameter selection, and
- collect and record baseline clinical information to which post-fitting examination results can be compared.

A prefitting examination should include spherocylinder refraction and VA, keratometry, and biomicroscopic examination.

- Never use conventional hard contact lens solutions that are not also recommended for use with prescribed lenses.
- Do not mix or alternate lens care systems or solutions unless indicated in the lens care system labeling.
- Do not use chemical disinfecting solutions with heat **unless** specifically indicated on product labeling for use in both heat and chemical disinfection.

### Lens Wearing Precautions

- Never wear lenses beyond the period recommended by the eye care professional.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care professional.
- Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

### Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care professional.

### Topics to Discuss with the Patient

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of ocular infection including but not limited to *Acanthamoeba* keratitis.
- Always contact the eye care professional before using any medicine in the eyes.

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## 2. Initial Lens Power Selection

- Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
- Place the lens on the eye and allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.
- Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

### 3. Initial Lens Evaluation

- To determine proper lens parameters, observe the lens relationship to the eye using a slit lamp.
  - Movement: The lens should provide discernible movement with:
    - Primary gaze blink
    - Upgaze blink
    - Upgaze lag
  - Centration: The lens should provide full corneal coverage.
- Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens.

### 4. Criteria of a Well-Fitted Lens

If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed.

### 5. Characteristics of a Tight (Steep) Lens

A lens which is much too steep may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward approximately 0.5mm while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

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## 6. Characteristics of a Loose (Flat) Lens

If the lens is too flat, it will:

- Decenter, especially on post-blink.
- Have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva.
- Have a tendency to be uncomfortable and irritating with fluctuating vision.
- Have a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

## 7. Follow-up Care

- a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for follow up.
  - 3 or 4 days post-dispensing
  - 10 days
  - 1 month
  - 3 months
  - Every six months thereafter

At the initial follow-up evaluations the eye care professional should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief.

- b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours 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** continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- d. After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and conduct a thorough biomicroscopy examination.
  1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.

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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. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around 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 are 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 for 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 that 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 the patient be a 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.

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2. 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.
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** are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

## WEARING SCHEDULE

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

### Daily Wear

There may be a tendency for the daily wear patient to overwear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients.

The wearing schedule should be determined by the eye care practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

### Extended Wear (Greater than 24 hours or while asleep):

The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. Bausch + Lomb recommends beginning extended wear patients with the recommended initial daily wear schedule, followed by a period of daily wear, and then gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The practitioner should examine the patient in the early stages of extended wear to determine the corneal response. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eye care practitioner. (See the factors discussed in the **WARNINGS** section.) Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eye care practitioner.

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## 7. Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions 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 use 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 eye care professional in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of the Bausch + Lomb SOFLENS® (polymacon) Contact Lens Patient Information Booklet.**

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## 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 or the patient with significant astigmatism (greater than one [1] diopter) in one eye may not be a good candidate for monovision with the Bausch + Lomb SOFLENS® (polymacon) Contact Lenses.

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. Visually 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 driver's license requirements with monovision correction should be advised to not 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 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

- a. **Ocular Preference Determination Methods**

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

- Method 1 - Determine which eye is the "sighting dominant 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 best with the near add lens over the right or left eye.

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## LENS CARE

### Patient Lens Care Directions

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care professional should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system selected by the practitioner, the specific instructions for such products and the particular characteristics of the patient. For complete information concerning the care, cleaning and disinfection of contact lenses refer to the Bausch + Lomb SOFLENS® (polymacon) Contact Lens Patient Information Booklet.

### a. Soaking and Storing Lenses

#### Instruction for Use:

Use only fresh contact lens disinfecting solution each time you soak (store) lenses.

#### WARNING:

Do not reuse or "top off" old solution left in lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-Off" is the addition of fresh solution to solution that has been sitting in the case.

### b. Rub and Rinse Time

#### Instruction for Use:

Follow the complete recommended lens rubbing and rinsing times in the labeling of the solution used for cleaning, disinfecting and soaking lenses to adequately disinfect lenses and reduce the risk of contact lens infection.

#### WARNING:

- Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect lenses. These solutions will not disinfect lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

- b. **Refractive Error Method**  
For anisometric corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the 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 the 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 diopter 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 eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

### 4. Near Add Determination

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

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 to this mode of correction.

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## c. Lens Case Care

### Instruction for Use:

- Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
- Replace lens case according to the directions given by your eye care professional or the labeling that came with your case.
- Contact lens cases can be a source of bacterial growth.

#### WARNING:

Do not store lenses or rinse lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

### d. Water Activity

#### Instruction for Use:

Do not expose contact lenses to water while wearing them.

#### WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submerged in water when swimming in pools, lakes or oceans, discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing lenses during any activity involving water.

### e. Discard Date on Solution Bottle

#### Instruction for Use:

Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking contact lenses.

#### WARNING:

Using solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

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## LENS DEPOSITS AND USE OF ENZYMIC CLEANING PROCEDURE

Enzyme cleaning may be recommended by the eye care practitioner. 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.

## 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.

## CARE FOR A DRIED OUT (DEHYDRATED) OR DRY LENS

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, such as a counter top, apply saline before handling.

To rehydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least one hour until it returns to a soft state.
- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, the lens should not be used until examined by the eye care practitioner.

## CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in their eye. The patient should be instructed to not use plain water, or anything other than the recommended solutions. The patient should be instructed to contact the eye care practitioner if the lens does not begin to move upon blinking after several applications of the solution.

## PRACTITIONER FITTING SETS

Lenses must be discarded after a single use and must not be used from patient to patient.

## 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 THEN REMOVE LENSES PROMPTLY. CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

## HOW SUPPLIED

Each Bausch + Lomb SOFLENS® (polymacon) Contact Lens is supplied in a plastic container or a glass package. The plastic container has a solution of phosphate buffered saline with 01% polyvinyl alcohol or a solution of borate buffered saline, while the glass vial has a 0.9% sodium chloride solution. The container is marked with the manufacturing lot number of the lens, the base curve, diopter power, diameter and expiration date.

## REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb SOFLENS® (polymacon) Contact Lenses or experienced with the lenses should be reported to:

Bausch & Lomb Incorporated  
1400 North Goodman Street  
Rochester, NY 14609 USA

### Toll Free Telephone Number

In the Continental U.S., Alaska, Hawaii  
1-800-828-9030  
In New York State  
1-800-462-1720