PROFESSIONAL FITTING GUIDE

BAUSCH + LOMB

Revive

CUSTOM SOFT CONTACT LENSES

# REVIVE™ (hioxifilcon B, hioxifilcon D) Soft (hydrophilic) Contact Lens for Daily Wear

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**Important: Please read this guide carefully and keep this information for future use.**

## DESCRIPTION

REVIVE™ sphere (hioxifilcon B, hioxifilcon D) Soft (hydrophilic) Contact Lenses are manufactured with a spherical front surface for the correction of visual acuity in persons who are myopic or hyperopic.

REVIVE™ toric (hioxifilcon B, hioxifilcon D) Soft (hydrophilic) Contact Lenses have a toric posterior surface generated for the purpose of correcting vision in an eye that is astigmatic. REVIVE™ toric lenses are designed with a thin zone for orientation.

REVIVE™ multifocal (hioxifilcon B, hioxifilcon D) Soft (hydrophilic) Contact Lenses are front surface aspheres consisting of multiple aspheric zones with the most plus power in the center progressing to more minus in the periphery with a spherical base curve.

REVIVE™ toric multifocal (hioxifilcon B, hioxifilcon D) Soft (hydrophilic) Contact Lenses are front surface aspheres consisting of multiple aspheric zones with the most plus power in the center progressing to more minus in the periphery with a toric posterior surface generated for the purpose of correcting vision in an eye that is astigmatic. REVIVE™ toric multifocal lenses are designed with a thin zone for orientation.

REVIVE™ Soft (hydrophilic) Contact Lenses are available in the following materials: hioxifilcon B, hioxifilcon D and are available clear or with a blue visibility-handling tint, (reactive blue 4) or [phthalocyaninato (2-)] copper and are flexible hemispherical shells of the following dimensions:

Chord Diameter: 10.0 mm to 16.0 mm

Center Tk, for Low Minus Lens: 0.10 mm

Center Tk, for Plus Lens: Up to 0.50 mm

Base Curve: 6.5 mm to 9.7 mm

Spherical Powers (toric lenses): -30.00 D to +30.00 D

Spherical Powers (spherical lenses): -30.00 D to +30.00 D

Cylinder Powers (toric lenses): -0.50 D to -10.00 D

Axis (toric lenses): 1° to 180°

Add Powers (multifocal lenses): +1.00 D to +4.00 D

REVIVE™ Soft Contact Lens (hioxifilcon B) and REVIVE™ Soft Contact Lens (hioxifilcon D) are non-ionic lens materials made from a co-polymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-dihydroxypropyl methacrylate (Glycerol Methacrylate, GMA). REVIVE™ Soft Contact Lens (hioxifilcon B) consists of 51% hioxifilcon B and 49% water and REVIVE™ Soft Contact Lens (hioxifilcon D) consists of 46% hioxifilcon D and 54% water by weight when immersed in buffered normal saline.

**The physical/optical properties of the lenses are:**

| | (hioxifilcon B) | (hioxifilcon D) |
|---|---|---|
| Refractive Index | 1.507 (dry)<br>1.425 (hydrated) | 1.510 (dry)<br>1.408 (hydrated) |
| Light Transmittance | > 95%<br>> 70% tinted | > 95% |
| Water Content | 49% | 54% |
| Specific Gravity | 1.308 (dry)<br>1.136 (hydrated) | 1.300 (dry)<br>1.136 (hydrated) |
| Oxygen Permeability | 15 | 21 |

## ACTIONS

In its hydrated state, the REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lenses, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

## CAUTION

Due to the small number of patients enrolled in clinical investigations of lenses, 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, since individual patient response may vary.

## INDICATIONS

REVIVE™ sphere lens for daily wear is indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with refractive ametropia (myopia or hyperopia). The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.

REVIVE™ toric lens for daily wear is indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with refractive ametropia (myopia or hyperopia) and/or possesses refractive astigmatism not exceeding 10 diopters.

REVIVE™ multifocal lens for daily wear is indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with refractive ametropia (myopia or hyperopia) and presbyopia. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.

REVIVE™ toric multifocal lens for daily wear is indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia.

REVIVE™ Soft Contact Lenses for daily wear are available for either conventional wear or planned replacement modalities.

## CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lenses 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 lenses.
- Allergic reactions of ocular surfaces or adnexa 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 REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lenses.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.

## 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 lenses while sleeping.** Clinical studies have shown that the risk of serious adverse reactions is increased when daily wear lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove the lenses** and promptly contact his or her eye care practitioner.

## PRECAUTIONS

**Special Precautions for Eye Care Practitioners**

- Clinical studies have demonstrated that contact lenses manufactured from hioxifilcon B and hioxifilcon D are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material. 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.
- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Aphakic patients should not be fitted with REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lenses until the determination is made that the eye has healed completely.
- 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 a sterile saline solution that is recommended for in-eye use.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove the lens or should have someone else available who can remove the lens for him or her.
- Eye care practitioners should instruct the patient to **remove the lens immediately** if the eye becomes red or irritated.

**Eye care practitioners should carefully instruct patients about the following lens care regimen and safety 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.
- Always use **fresh, unexpired** lens care solutions.
- Always follow directions in the package insert for the use of contact lens solutions.
- Use **only chemical (not heat) lens care systems** labeled for use with soft contact lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solution for lubricating or rewetting 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.
- Always 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 lens. Follow the lens care directions in CARE FOR A DRIED OUT (DEHYDRATED) LENS in the Patient Information Booklet if the lens surface becomes dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions in CARE FOR A STICKING (NON-MOVING) LENS. The lens should move freely on the eye for the continued health of the eye.
- 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-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lens may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Information Booklet for the REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lenses and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing the 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 eye care practitioner 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.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- 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.
- Do not touch the lens with fingernails.
- Always discard lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care practitioner.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness, or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient do not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to ensure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

## ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

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 the lens was first placed on the 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 the 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 lens; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult the eye care practitioner**.

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 lenses 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 staining, 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 referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or a steroid/antibiotic combination 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.

## FITTING PROCEDURE (SINGLE VISION AND MULTIFOCAL)

**Patient Selection**

The eye care practitioner 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. The practitioner should first assess the patient's needs and characteristics necessary to fit with REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

**Pre-Fitting Examination**

A pre-fitting examination is necessary to:

- Determine if the patient is a suitable candidate in terms of motivation, physical state, and willingness to comply with instructions concerning wear time and hygiene;
- Carefully evaluate the lids, lashes, conjunctival areas as well as the anterior segment of the eye for suitability for contact lens wear;
- Take 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 pre-fitting examination should include a thorough case history, a spherocylindrical refraction, keratometric readings, tear assessment, and biomicroscopy of the anterior segment.

**Initial Power Determination**

The initial power selection should be as close as possible to the patient's spectacle prescription after taking into account spherical equivalent and vertex calculations; if necessary, contact lens add power (for multifocal lenses) should be based on the patient's spectacle prescription as well. Remember to compensate for vertex distance if the refraction is greater than +4.00D or less than -4.00D.

To determine the add power on multifocals:

- For distance powers of plano or minus power, use the refractive add power
- For distance powers +0.25D or greater, use the refractive add power minus 0.25D
- For distance powers greater than +2.00D, and refractive add powers greater than +2.25D, use the refractive add power minus 0.50D

**Base Curve Selection**

A well-fitted lens provides good movement, centration, and comfort. Corneal curvature measurements should be performed to establish the patient's baseline ocular status. Initial base curve selection is based on the flattest "K" readings and can be obtained by using the following chart:

| K Reading | Base Curve (mm) | Diameter (mm) |
|---|---|---|
| 41.75 and flatter | 8.9 | 14.5 |
| 42.00 to 45.00 | 8.6 | 14.5 |
| 45.25 and steeper | 8.3 | 14.5 |

Place a lens on each of the patient's eyes and allow at least a 10-minute period of adjustment and equilibration. The base curve recommendations are a guide and may not be true on all eyes. 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. Patient comfort and lens tolerance should be acceptable from the onset.

**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. If after the lens has settled on the eye, the patient reports lens sensation, or if the lens is moving or decentering excessively, the lens should not be dispensed. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, the lens should not be dispensed.

## 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.

**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.

Toric Lens: With your finger, gently rotate the lens approximately 45° to the temporal side. It should reorient with 5 to 10 blinks back to the same stabilized position.

**Characteristics of a Loose (Flat) Lens**

A lens that is too flat 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. A flat fitted lens will have a tendency to be uncomfortable and irritating with fluctuating vision. A flat fitted lens has a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

## FITTING PROCEDURE (TORICS)

See the fitting procedure above for Single Vision and Multifocal lenses. Most aspects of the fitting procedures are the same for all types of soft contact lenses, but there are additional steps to follow to ensure the proper fit of Toric lenses.

**Determine Contact Lens Power:**

The toric trial lens is used to optimize lens fitting characteristics and determine axis orientation. Lens power is determined by the spectacle refraction. It is preferable to use the spectacle Rx as the basis for the contact lens power. The sphere and cylinder power of the spectacle Rx becomes the closest sphere and cylinder power of the contact lens. There are two exceptions:

- If spectacle cylinder power falls between available contact lens cylinder powers, prescribe the lesser contact lens cylinder power. The sphere power can be increased -0.25D to compensate if desired. Of course, this can vary depending on your interpretation of the patient's subjective responses.

  Example: Spectacle Rx: -2.00 -1.00 X 180
  Contact Lens Power Ordered: -2.25 -0.75 X 180

- When the spectacle lens power in any principal meridian is greater than 4.00D, the spectacle refraction should be vertexed to the corneal plane. This can affect both the sphere and cylinder powers ordered.

  Example: Spectacle Rx: -5.00 -2.75 X 180
  Contact Lens Power Ordered: -4.75 -2.25 X 180

**Determine contact lens axis,** the peripheral guide marks should locate at 0° and 180°. Once oriented, rotational rocking should be limited to less than 5°.

Allow the lens to settle for at least 10 minutes to achieve a state of equilibrium. Note the orientation of the guide marks relative to the 0° to 180° meridian. Regardless of which eye the lens is on, if the rotation is clockwise but stable, note the amount of rotation, add it to the refractive cylinder axis and order the resulting axis. If the rotation has stabilized counterclockwise, again note the rotation, subtract it from the refractive axis and order the resulting axis. The guide marks can be used to help you calculate the axis of the desired Rx lens.

Example: Spectacle Rx: -2.50 -1.25 X 80
Rotation: 20° clockwise
Final Lens Prescription: -2.50 -1.25 X 100
Select patient's lenses.

**Evaluate orientation of final Rx lenses.** The orientation of the prescription should be the same as that observed for the trial lenses. For example, if the trial lens rotated clockwise 15° then the final prescription lens should also rotate clockwise 15°.

## FOLLOW-UP EXAMINATIONS

Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear. Prior to a follow-up examination, the contact lenses should be worn for at least four continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

With the lenses on the eyes, evaluate fitting performance to ensure that the CRITERIA OF A WELL-FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

After the lens removal, conduct a thorough biomicroscopic examination. Be sure to check for:

- The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization, which may be indicative of excessive corneal edema;
- The presence of corneal staining and/or limbal-conjunctival hyperemia, which may be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitting lens;
- Papillary conjunctival changes, which 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 patients should be re-fitted with a more appropriate lens.

## IN-OFFICE CARE FOR TRIAL LENSES

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

Each contact lens is shipped in a package containing the lens in sterile saline solution. Hands should be thoroughly washed, rinsed, and dried with lint-free towels prior to handling a lens. In order to ensure sterility, the lens package should not be opened until immediately prior to use.

- Clean and rinse the lens thoroughly with solutions recommended for use with soft contact lenses.
- Following instructions for disinfection provided with the disinfecting solution, place the lens in a suitable container with the solution.
- Rinse the lens before inserting in a patient's eye.

## WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Regular checkups, as determined by the eye care practitioner, are extremely important.

**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.

**Frequent/Planned Replacement Wear**

When removed between replacement periods, lenses must be cleaned and disinfected before reinsertion, or be discarded and replaced with a new lens.

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE REVIVE™ (HIOXIFILCON B, HIOXIFILCON D) SOFT CONTACT LENSES ARE SAFE TO WEAR DURING SLEEP.

## MONOVISION FITTING GUIDELINES

The design of the REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lens allows simultaneous binocular vision allowing the patient to view distant, intermediate and near objects, without translation of the lens on the surface of the eye. Therefore, it eliminates the need for the eye care practitioner to fit a patient for monovision. However, should the eye care practitioner choose to use monovision for a patient, the following guideline is recommended.

**Patient Selection**

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 REVIVE™ (hioxifilcon B, hioxifilcon D) Soft 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:

- Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- 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.

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.

**Eye Selection**

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

Ocular Preference Determination

- 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.

Refractive Error Method

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

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.

**Trial Lens Fitting**

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

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next, determine the near add. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. 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 the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, would not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

**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.

**Other Suggestions**

The success of the monovision contact lens wearer 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 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 contact lenses 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 vision at all distances in all gazes.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the Patient Information Booklet for the REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lens.

## HANDLING OF LENS

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 lubricating and rewetting drops before removal of the lens. Care should be used not to pinch the lens when removing it from the eye. Pinching the lens can reduce the life of the lens. Always start with the right lens first in order to avoid mixing the lenses. In removing the lenses, 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, ensure that it is clean, clear, and wet.

**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 practitioner 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 REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lenses Patient Information Booklet.

**Soaking and Storing Lenses**

*Instruction for Use:*

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

**WARNING:**

Do not re-use or "top-off" old solution left in lens case since solution re-use 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.

**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.

**Lens Case Care**

*Instruction for Use:*

Clean contact lens cases with digital rubbing with 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. Air-drying or recapping the lens case lids after use without any additional cleaning methods should be avoided. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry. Replace the lens case according to the directions given by your eye care practitioner 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.

**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 submersed in water when swimming in pools, lakes, or oceans, discard them and replace them with a new pair. Ask your eye care practitioner for recommendations about wearing lenses during any activity involving water.

**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.

## CARE FOR A STICKING (NON-MOVING) 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 or drops, and to **not** attempt to remove the lens except on the advice of the eye care practitioner.

## STORAGE

REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lenses must be stored only in the recommended solutions. If left exposed to the air, the lens will dehydrate. If lens dehydrates, follow the lens care direction in the CARE FOR A DRIED OUT (DEHYDRATED) LENS section of the Patient Information Booklet.

## LENS CARE PRODUCTS

The eye care practitioner should recommend a care system that is appropriate for REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. Multi-purpose solutions are the preferred choice for use. If using hydrogen peroxide solutions, exposure to peroxide should be limited by using a disc-based system.

## 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.**

## REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lenses or experienced with the lenses, should be reported to: Bausch & Lomb Incorporated, 6 Lancaster Pkwy, Lancaster, NY 14086 USA; Telephone: 1-800-253-3669.

## HOW SUPPLIED

Each REVIVE™ (hioxifilcon B, hioxifilcon D) Soft Contact Lens is supplied sterile in a glass vial containing 0.9% buffered saline USP. The glass vial is marked with the base curve, power, diameter, manufacturing lot number, and the expiration date of the lens.

## SYMBOLS USED ON LABELING

| Symbol | Description |
|---|---|
|  | Manufacturer |
|  | Batch code |
|  | Prescription Only (USA) |
|  | Use-by date |
|  | Caution |
|  | Sterilized using steam |
| CYL | Cylinder power |
| AX | Cylinder axis |
| BC | Base curve |
| ADD | Add power |
| DIA | Diameter |
| PWR | Power |



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