AQUILUS™

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FITTING GUIDE / PACKAGE INSERT

Daily Wear Frequent Replacement

LUMIERE™ Monthly Disposable Contact Lens

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

IMPORTANT: This fitting guide and package insert has been developed to provide eye care professional with information concerning the characteristics of LUMIERE™ Monthly Disposable Contact Lens and to explain fitting procedures. However, it should be made available to patients upon request. The eye care professional should provide the patient with the patient instructions concerning the lens prescribed as well as the recommended wearing schedule.

1. DESCRIPTION

The lens is made of 43% Hioxifilcon A and 57% water by weight when soaked in packaging phosphate buffered saline solution. The FDA approved reactive blue RB 246 is used to provide the handling tint. The device come with aspheric front and base curves to provide spherical aberration control for better vision at low lighting condition.

The lens geometry includes a tri-curve aspheric front surface with bi-blend curve and single aspheric free-form back surface with taper edge design. The optical zone curve provide the optimum center thickness for the required vision correction power and the lenticular zone curves provide the required lens shape to ensure good handability. The edge taper to ensure good comfort and optimum tear flow.

2. MATERIAL PROPERTIES

The physical properties of the lens are as follows:

Specific Gravity	1.096
Refractive Index	1.4000
Light Transmission	> 94%
Water Content	57%
Oxygen Permeability (Dk)	23.29

3. AVAILABLE LENS PARAMETERS

The LUMIERE™ Monthly Disposable Contact Lens is a hemispherical shell, designed to be worn in front of the cornea and on the adjacent portion of the surrounding bulbar conjunctiva with the following dimensions:

Diameter	14.20 mm
Center Thickness	0.09 mm
Base Curve	8.60 mm
Power Range	+6.00D to -10.00D

4. ACTIONS (HOW THE LENS WORKS)

In its hydrated state, the LUMIERE™ Monthly Disposable Contact Lens when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

5. INDICATIONS (USES)

The device is designed for daily wear for myopic and hypermetropic visual correction in non-aphakic person with non-diseased eyes with corrective power within the limits of the device power specification.

The product is for single patient use. The monthly frequent replacement lens is intended for daily wear and the lens is to be cleaned, rinsed and disinfected each time it is removed from the eye and replaced every month. However, the qualified Eye Care Professional is strongly encouraged to prescribe the appropriate device replacement schedule based on the ocular response of the patient.

6. CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the LUMIERE™ Monthly Disposable Contact Lens when any of the following conditions exist:

a) Acute and sub-acute inflammation or infection of the anterior chamber of the eye.

b) Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids.

c) Any previously diagnosed condition that makes contact lens wear uncomfortable.

d) Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.

e) Any active corneal infection (bacterial, fungi or viral).

f) Allergic reactions of ocular surfaces or surrounding tissue that may be induced or exaggerated by wearing contact lenses.

g) Allergic reactions to any ingredient, such as mercury or Thimerosal in contact lens solutions.

h) Corneal hypoesthesia (reduced corneal sensitivity), if non-aphakic.

i) If eyes become red or irritated.

j) Severe insufficiency of lacrimal secretion (dry eyes).

7. WARNINGS

After a full eye examination, including appropriate medical background evaluation, patients should be thoroughly briefed by the eye care professional of all the risks associated with contact lens wear. The following warnings should also be advised:

a) Problems with contact lenses or lens care product, including the lens case could result in serious injury to the eye. It is essential that patient follow their eye care professional's direction and all labeling instructions for proper use of lens and lens care products, including the lens case.

b) Patients should fill their lens case with fresh solution each time they store their lenses and never re-use solution. Upon removal of lenses from the lens case, the patient should empty, clean and rinse the lens case with fresh solution, then allow it to air dry. Eye problems, including a sore or lesion on the cornea (corneal ulcers) can develop rapidly and lead to loss of vision if proper care is not exercised.

c) Daily wear lenses are not indicated for overnight wear and patients should be instructed not to wear the LUMIERE™ Monthly Disposable Contact Lens while sleeping. Clinical studies have shown that the risk of an infected sore or lesion on the cornea (ulcerative keratitis) and other serious adverse reactions is greater when these lenses are worn overnight.

d) Studies have shown that contact lens wearers who smoke have a higher occurrence of adverse reactions than non-smokers and possibility of ulcerative keratitis.

e) Strict adherence with care regimen including cleaning of the lens case, wearing restrictions, wearing schedule and regular follow-up visits should be emphasized to the patient.

f) Should the patient experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, the patient should **immediately remove** the lenses and promptly contact his or her eye care professional.

8. PRECAUTIONS

a) <u>For the Eye Care Professional</u>

i) 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 designs and parameters, the eye care professional should take into consideration 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.

ii) 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.

iii) Fluorescein should not be used while the patient is wearing the lenses as the lenses will become discoloured. Whenever fluorescein is used, flush the eyes with sterile saline solution. Wait for at least 5 minutes before reinserting the lenses. If it is not possible to flush the eyes, wait a minimum of 1 hour before reinserting the lenses. If replaced too soon, the lenses may absorb the residual fluorescein.

iv) Before leaving the eye care professional's office, the patient should be able to remove the lenses promptly or have someone else available who can remove the lenses for him or her.

v) The patient should be instructed about the 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.

- Refrain from using solutions recommended for conventional hard contact lenses only.
- Always use fresh unexpired lens care solutions.
- Always adhere to the directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of heat care systems can damage your contact lens.
- Sterile unpreserved solutions when used, should be discarded after the time specified in the labeling directions.
- Always keep the lens completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage the lenses. When this happens, damaged lenses must be discarded.

vi) Always wash and rinse hands before handling the 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.

vii) Ensure that the fingers or hands are free of foreign materials prior to touching the lenses, as microscopic scratches of the lenses may occur, resulting in distorted vision and/or injury to the eye.

viii) Always handle the lenses carefully and avoid dropping them.

ix) Do not touch the lens with fingernails.

x) Do not use saliva or anything other than the recommended solutions for lubricating or rewetting the lenses. Do not put lenses in the mouth.

xi) Carefully follow the handling, insertion, removal, cleaning and wearing instructions in the Patient Instruction Guide and those prescribed by your eye care professional.

xii) Never use tweezers or other tools to remove the lenses from the lens container unless specifically indicated for that use. Pour the lens into the hands.

xiii) Always discard lenses worn on a frequent replacement wearing schedule after the recommended wearing schedule prescribed by the eye care professional.

xiv) Never wear lenses beyond the period recommended by the eye care professional. Lenses should be removed immediately if the eyes become red or irritated.

xv) If the lens sticks (stops moving) on the eye, follow the recommended directions on "Care for a Sticking (Non-moving) Lens". The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be advised to immediately consult his or her eye care professional. Do not attempt to remove the lens except on the instructions of the eye care professional.

xvi) Avoid all harmful or irritating vapors and fumes while wearing lenses.

xvii) If aerosol products, such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

xviii) Ask the eye care professional about wearing contact lenses during sporting and water related activities.

xix) Always consult the eye care professional before applying any medication in the eyes.

xx) Inform the family doctor (health care professional) about being a contact lens wearer.

xxi) Always inform the employer of being a contact lens wearer. Some profession may require use of eye protection equipment or may require that the patient not wear contact lenses.

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

b) <u>For Frequent Replacement Wear</u>

i) If the lenses are prescribed for frequent replacement wear, they are to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care professional. The lens may be disinfected using a chemical disinfection system. It is important that the patients are instructed to always have an available pair of replacement lenses.

ii) Always use fresh unexpired lens care solutions.

iii) Use the recommended system of lens care, chemical (not heat) and carefully following instructions on solution labeling. Different solutions cannot always be used together and not all solutions are safe for use with all lenses. **Hence, do not mix or alternate the lens care systems unless specified on the solution labeling.**

iv) Lenses should be cleaned, rinsed and disinfected after each removal. Cleaning and rinsing are necessary to eliminate mucus, secretions, films or deposits that may have accumulated on your lenses during wearing; whilst disinfecting is essential to destroy harmful bacteria.

v) Always remove, clean, rinse and disinfect lenses according to the schedule prescribed by the eye care professional.

vi) The eye care professional should recommend a care regimen that is appropriate for LUMIERE™ Monthly Disposable Contact Lenses.

vii) Always clean the same lens first to avoid mix-ups.

viii) Upon cleaning, rinse the lens thoroughly with a recommended rinsing solution to remove the cleaning solution, mucus, secretions, film and deposits from the lens surface, and place the lens into the correct chamber of the lens storage case.

ix) After cleaning and rinsing, disinfect lenses using the system recommended by the manufacturer and/or eye care professional.

x) Do not disinfect your lenses using heat. If disinfection is by using hydrogen peroxide lens care system, the lenses **must be neutralized before wearing**. Strictly follow the recommendations on the hydrogen peroxide system labeling.

xi) To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If the lenses are not worn immediately following disinfection, the patient should refer to the instructions in the solution package insert or eye care professional for information about storing the lenses.

xii) Upon removal of lenses from the lens case, empty, clean and rinse the lens case with solutions recommended by the lens case manufacturer or eye care professional, then allow it to air dry. When reusing the lens case, always refill it with fresh solution. Lens case should also be replaced at regular intervals as recommended by the lens case manufacturer or your eye care professional.

xiii) Eye care professionals may recommend a lubricating/rewetting solution which may be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

Note: Some solutions may have more than one function specified on the label. Read the label on the solution bottle and follow the instructions.

9. POTENTIAL ADVERSE REACTIONS

a) The patient should be aware of the following problems that may occur when wearing contact lenses:

i) The eyes may sting, burn and/or itch.

ii) There may be:

- less comfort than when the lens was first placed on eye.
- a feeling of something in the eye (scratched area, foreign body).
- the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion.
- the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- excessive watering, unusual eye secretions or redness of the eye.

iii) Poor visual acuity, blurred vision, rainbows or halos around objects, photophobia (sensitivity to light) or dry eyes

iv) If the patient experiences or notices any of the above, he or she should **immediately remove the lens**.

v) If the discomfort or problem stops, look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Discard the lens and insert a fresh new lens on the eye. If the problem persists with the fresh new lenses, the patient **should immediately remove the lenses and consult his or her eye care professional,** who must establish the need for examination, treatment or referral without delay. Refer to "*Important Treatment Information for Adverse Reactions*".

b) <u>Important Treatment Information for Adverse Reactions</u>

i) Sight-threatening ocular complications associated with contact lens wear can develop rapidly and hence, early detection and treatment of problems are critical. Infectious corneal ulcer is one of the most serious potential complications and may be ambiguous in its early stage. Sign and symptoms of infectious corneal ulcer include discomfort, pain, inflammation, pus-filled discharge, photophobia, cells and flares and corneal infiltrates.

ii) Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Therefore, such epithelial defect, if not properly treated may develop into an infected ulcer. In order to prevent the condition from worsening, a patient with symptoms of abrasions or early ulcers should be assessed as a potential medical

emergency, given the proper treatment and referred to the corneal specialist where necessary. Standard therapy for corneal abrasions such as eye patching or the use of steroids may aggravate the condition. The patient wearing the contact lens on the affected eye upon examination should have the lens removed immediately and the lens retained for analytical investigation and culturing.

10. PATIENTS SELECTION

a) If the patient requires only vision correction, but will not or cannot follow the recommended care schedule for the lenses, or are unable to put on and remove the lens or have someone available to place and remove them, they should not be provided with the lenses.

b) Failure to follow handling instructions may cause infections and complications, resulting in eye damage in some severe conditions. Hence, patient communication is critical as it relates not only to patient selection but also to ensure adherence. It is also necessary to discuss the information outlined in the Patient Instruction Guide with the patient at the point of initial examination.

c) The eye care professional should establish the motivation, determine the general health and cooperation of patients selected to wear LUMIERE™ Monthly Disposable Contact Lens. He should also exercise care in selecting, examining and instructing contact lens patients, as well as review their vocation, desired lens wearing time (e.g. full or part time) and desired lens usage (e.g. reading, hobbies or recreation). Understanding the patient's history is unquestionably important as it aids in determining their needs and expectations. Lastly, the patient's willingness to follow the eye care professional's instructions and personal hygiene are essential to their enjoyment of contact lens wear.

d) Initial evaluation of the 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.

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

11. FITTING PROCEDURE

a) <u>Pre-fitting Examination</u>

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

i) Determine whether a patient is a suitable candidate for daily wear contact lenses (factors such as patient hygiene, physical and mental state to be considered).

ii) Make ocular measurements for initial contact lens parameter selection.

iii) Collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include spherocylinder refraction and VA, keratometry and biomicroscopic examination.

b) Initial Lens Power Determination

i) Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.

ii) Select the appropriate power lens and place the lens on the eye. Allow the lens to remain on the eye substantially (about 10 to 20 minutes) to achieve the state of equilibrium. Small variations in the tonicity, pH of the lens solutions and individual tear composition may cause slight changes in fitting characteristics.

iii) Allow any increase in tear flow to subside before doing an evaluation on the lens. Time needed will differ according to patients.

c) Initial Lens Evaluation

i) To determine proper lens parameters, observe the lens relationship to the eye using a slit lamp.

- Movement: The lens should provide apparent movement with *primary gaze blink*, *upgaze blink* and *upgaze lag*.

- Centration: The lens should provide full corneal coverage.

d) Criteria of a Properly Fitted Lens

A properly fitted lens will center and completely cover the cornea. If it provides apparent movement after a blink, is comfortable and yields satisfactory visual acuity, it is deemed as well fitted lens and can be dispensed.

e) Characteristics of a Tight (Steep) Lens

A steep fitting lens may exhibit one or more the following characteristics - insufficient movement with the blink and resistance when pushing the lens up using fingertip pressure on the lower lid, thereby causing significant distortion. However, if the lens is slightly steep, the vision and comfort findings may be acceptable. The slightly steep lens may be differentiated from a properly fitted lens by having the patient gaze upwards. A properly fitted lens tend to slide downwards about 0.5mm while a steep lens, when blinked, will remain rather stable in relationship to the cornea.

f) Characteristics of a Loose (Flat) Lens

A lens which is too flat will tend to:

i) be off-centered, especially on a post blink.

ii) move excessively with the blink

iii) be uncomfortable and irritating with inconsistent vision.

iv) drop or lag greater than 2.0mm on upgaze post blink.

v) rest on the lower lid, rather than cover the cornea completely.

g) Follow-up Examination

i) Follow-up care is necessary to ensure continued successful contact lens wear and should include routine periodic progress examinations, management of specific problems, if any, and a review with the patient of the wearing schedule and handling procedures. The following is a recommended guideline for follow-up after post-dispensing.

- 3 or 4 days
- 10 days
- One month
- Every three to six months thereafter

Note: Any complications and specific problems should be managed on an individual patient basis.

ii) Prior to the follow-up examination, the contact lenses should be worn for at least four to six continuous hours and the eye care professional should solicit and record the patient's symptoms associated with contact lens wear.

iii) With the lenses in place on the eyes, evaluate the fitting performance to assure the "*criteria of a properly fitted lens*" continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

iv) Following the lens removal, examine the cornea and conjunctiva with the biomicroscope and fluorescein (unless contraindicated).

- The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.

- Papillary conjunctival changes may indicate an unclean and/or damaged lens.

- The presence of corneal staining and/or limbal-conjunctival hyperemia can imply of an unclean lens, a reaction to solution preservatives, excessive lens wear and/or a poorly fitted lens.

v) If any of the above observations are considered abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the "*criteria of a properly fitted lens*" are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

12. PRACTITIONER FITTING SETS

The LUMIERE™ Monthly Disposable Contact Lens must be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care professional

13. WEARING SCHEDULE

a) The Eye Care Professional should determine the wearing and replacement schedules. Regular check-ups, as defined by the eye care professional are extremely important.

b) Patients tend to over wear the lenses initially. Therefore, eye care professional should emphasize the importance of adhering to the initial maximum daily wearing schedule to these patients. The wearing schedule should be determined by the eye care professional based on the response of the patient. A copy of the schedule chosen by the eye care professional should be given to the patient.

c) The recommended maximum daily wearing time for the lenses is:

Day	No. of Hours
1	4 to 6 hours
2	6 to 8 hours
3	8 to 10 hours
4	10 to 12 hours
5 and beyond	All waking hours

14. MONOVISION FITTING GUIDELINES

a) <u>Patient Selection</u>

i) *Monovision Needs Assessment*
For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient with significant astigmatism (greater than 1.00D) in one eye may not be a good candidate for monovision correction with the LUMIERE™ Monthly Disposable Contact Lens.

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 correction. 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 drivers licence requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

ii) *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 eye glasses (multifocal, bifocal, trifocal, readers, progressives). Each patient should understand that monovision, as well as other presbyopic alternatives, 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 understand the limitations and advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

b) Eye Selection

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

i) *Ocular Preference Determination Methods*
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 hand-held trial lens equal to the spectacle near ADD 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.

ii) *Refractive Error Method*
For anisometropic correction, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

iii) *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 function best with the near lens on the left eye.

15. SPECIAL FITTING CONSIDERATIONS

a) 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 only require a distance lens.

Example: A *presbyopic emmetropic* patient who requires a +1.75D ADD would have a +1.75D lens on the near eye and the other eye left without a lens, whilst a *presbyopic* patient requiring a +1.50D ADD who is –2.50D myopic in the right eye and -1.50D myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

16. 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.

17. TRIAL LENS FITTING

a) 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.

b) Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine the distance correction and the near correction. Next determine the near ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

c) Once 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.

d) Only after these vision tests 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.

e) 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.

f) 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.

18. ADAPTATION

a) 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 adaptation 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.

b) 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.

c) 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.

19. OTHER SUGGESTIONS

a) The success of the monovision technique may be further improved by having your patient follow the suggestions below:

   i) Have a third contact lens (distance power) to use when critical distance viewing is needed.

   ii) Have a third contact lens (near power) to use when critical near viewing is needed.

   iii) 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 fulfil state licensing requirements with a monovision correction.

   iv) Make use of proper illumination when carrying out visual tasks.

b) Success in fitting monovision can be improved by the following suggestions:

   i) Reverse the distance and near eyes if a patient is having trouble adapting.

   ii) Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.

   iii) Emphasize the benefits of clear near vision and straight-ahead and upward gaze with monovision.

c) 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.

d) All patients should be given a copy of the "LUMIERE™ Monthly Disposable Contact Lens Patient Instruction Guide."

20. HANDLING OF LENSES

Each sterile lens is supplied in a foil-sealed blister containing buffered saline solution. The patient should be provided with appropriate and adequate instructions on personal cleanliness for lens handling. The eye care professional should recommend the suitable products and procedures for each individual patient in accordance to the specific lens wearing schedule and care regimen.

For complete information on "*personal cleanliness and lens handling*" and "*caring for your lens*", please refer to the Patient Instruction Guide.

21. CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (i.e. stops moving) on the eye, the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution and wait until the lens starts to move freely on the eye before removing it. If non-movement of the lens persists upon blinking after several applications of the solution, the patient should not attempt to remove the lens but seek **immediate** attention of the eye care professional.

22. CARE FOR A DEHYDRATED (DRIED OUT) LENS

If the LUMIERE™ Monthly Disposable Contact Lens is off the eye and exposed to air for a while, it will become brittle and dry. When this occurs, the patient should be instructed to discard the lens and use a fresh new one.

23. EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **flush eyes immediately with tap water and immediately contact the eye care professional or visit a hospital emergency room without delay.**

24. REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and reactions observed in patients wearing LUMIERE™ Monthly Disposable Contact Lens or experienced with the lenses should be reported to:

Aquilus Lens International Pte Ltd
132 Joo Seng Road #05-01
Singapore 368358
Tel: +65 6383 2300
Fax: +65 6339 6609
Email: regulatory@aquiluslens.com

25. HOW SUPPLIED

Each sterile lens is supplied in a blister pack (i.e. foil-sealed package) containing buffered saline solution. Each blister pack is marked with the manufacturer's name, base curve, diameter, diopter power, lot number and expiration date, the word "Sterile" together with the method of sterilization and "Caution" symbol.

The following symbols may appear on the label or carton.

SYMBOLS KEY

Symbol	Definition
℞ Only	Caution: Certain country law restricts this device to sale by or on the order of a licensed practitioner
BC	Base Curve
DIA	Diameter
D	Diopter (Lens Power)
LOT	Lot Number or Batch Number
	Use By (Expiration Date), expressed in YYYY/MM
⚠	Caution or Attention: See Instructions for Use
STERILE	Sterilized Using Moist Heat
♻	Product packaging is recyclable