PACKAGE INSERT / FITTING GUIDE

BAUSCH + LOMB

INFUSE™

(kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses

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

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IMPORTANT

This Package Insert and Fitting Guide has been developed to provide practitioners with information covering characteristics of the Bausch + Lomb INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens and to illustrate fitting procedures. It is effective as of revision date on cover and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

This package insert and fitting guide 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 and the recommended wearing schedule.

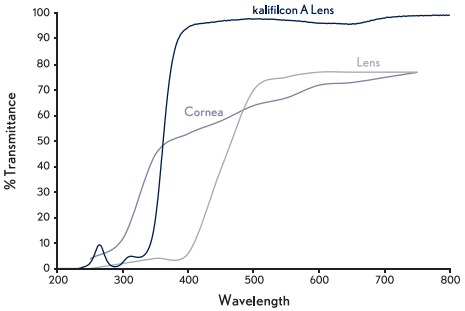
DESCRIPTION

The Bausch + Lomb INFUSE™ lens material, kalifilcon A, is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-vinylpyrrolidone and is 55% water by weight when immersed in a saline solution. A benzotriazole UV-absorbing monomer is incorporated into the manufacturing process to block Ultraviolet (UV) radiation. The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm. This lens is tinted blue with Reactive Blue Dye 246.

The physical/optical properties of the lens are:

Specific Gravity:	1.029
Refractive Index:	1.4011
Light Transmittance:	C.I.E. Y value - approximately 99%
Water Content:	55%
Oxygen Permeability (Dk):	107 x 10^{-11} [cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg) @ 35°C (Polarographic Method)

The lens is to be prescribed for single-use disposable wear and is to be discarded after each removal.



Typical transmittance profile of kalifilcon A (55% water) lenses vs a Human Cornea and Human Lens:

1. Human crystalline lens from a 25-year-old person as described in Waxler M., Hitchins V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, fig. 5
2. Human Cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig. 2-21
3. Kalifilcon A (55% water) Soft Contact Lens, -1.00D Power, Nominal Center Thickness 0.08 mm

These lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

Warning:
UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear, such as UV-absorbing goggles or sunglasses, because they do not completely cover the eye and surrounding area. The patient should continue to use UV-absorbing eyewear as directed.

Note:
Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation.

Note:
The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Patients should be instructed to consult the eye care practitioner for more information.

CONTACT LENS PARAMETERS AVAILABLE

The Bausch + Lomb INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens is a hemispherical shell of the following dimensions:

Diameter:	14.2mm
Center Thickness:	0.08mm to 0.018 (varies with power)
Base Curve:	8.6mm
Powers (Spherical):	+6.00D to -6.00D in 0.25D steps -6.50D to -12.00D in 0.50D steps

Additional parameters may be introduced over time, check periodically for product availability.

HOW THE LENS WORKS (ACTIONS)

In its hydrated state, the Bausch + Lomb INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm.

INDICATIONS

SVS

The Bausch + Lomb INFUSE™ (kalifilcon A) Soft (Hydrophilic) Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) 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)
- 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
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS

After a thorough eye examination, including appropriate medical background, patients should be fully apprised by the prescribing eye care practitioner of all the risks with contact lens wear. **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.
- Patients should be instructed not to expose their contact lenses to water while wearing them. Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If their contact lenses have been submersed in water when swimming in pools, lakes, or oceans, the contact lenses should be discarded and replaced with a new pair. Recommendations for wearing lenses during any water activity should be discussed with the patient.

PRECAUTIONS

Special Precautions for Eye Care Practitioners

- 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 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 should 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 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.
- Eye care practitioners 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 practitioner.
- 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.

- Aphakic patients should not be fitted with Bausch + Lomb INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses until the determination is made that the eye has healed completely.
- The lenses are prescribed for disposable wear and are to be disposed of once they are removed from the patient's eye. It is important that patients be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens, or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
- Eye care practitioners should carefully instruct patients about the following safety precautions. It is strongly recommended that patients be provided with a copy of the Patient Information Booklet for Bausch + Lomb INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, available from Bausch + Lomb, and understand its contents prior to dispensing the lenses.

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-based cosmetics are less likely to damage lenses than oil-based products.
- Be sure that before leaving the eye care practitioner'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 INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses and those prescribed by the eye care practitioner.
- 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.

Lens Wearing Precautions

- Never wear lenses beyond the period recommended by the eye care practitioner.
- 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. If non-movement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care practitioner.
- 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.

Topics to Discuss with the Patient

- 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.
- 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 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.

Who Should Know That the Patient is Wearing Contact Lenses

- Patients should inform their doctor (health care professional) 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 the patient does not wear lenses.

ADVERSE REACTIONS

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

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when 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 your eye. You should discard the lens and insert a new lens on the eye. If the problem continues, you should **immediately** remove the lenses and consult your 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 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 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/or lens care products retained for analysis and culturing.

SELECTION OF PATIENTS

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. 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.

Patients selected to wear Bausch + Lomb INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses should be chosen for their motivation to wear contact lenses, general health, and cooperation. The eye care practitioner 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 practitioner.

PRACTITIONER FITTING SETS

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

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

A pre-fitting examination should include spherocylinder refraction and Visual Acuity (VA), keratometry, and biomicroscopic examination.

2. Initial Lens Power Selection

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

b. Select the appropriate lens and place on the eye. Allow the lens to remain on the eye long enough 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.

c. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial Lens Evaluation

a. 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.

b. 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.

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

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

Daily Wear

There may be a tendency for the daily wear patient to over-wear 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.

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 INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) 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.

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

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

a. *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 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.

b. *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.

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.

Example: 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.

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 distant 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, 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.

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 practitioner in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of** the Bausch + Lomb INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens Patient Information Booklet.

WEARING SCHEDULE

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

Daily Wear

There may be a tendency for the daily wear patient to over-wear 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. The lens is to be prescribed for single-use disposable wear and is to be discarded after each removal.

HANDLING OF LENSES

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 for each individual patient in accordance with the particular lens wearing schedule.

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 and to not attempt to remove the lens except on the advice of the eye care practitioner.

EMERGENCIES

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 AN 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 Bausch + Lomb INFUSE™ (kalifilcon A) One-Day Soft (Hydrophilic) 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
1-800-553-5340
In Canada
1-888-459-5000 (Option 1 - English, Option 2 - French)

HOW SUPPLIED

Each sterile lens is supplied in a plastic package containing phosphate buffered saline solution with potassium chloride, poloxamine, poloxamer 181, glycerin, and erythritol. Each container is marked with the manufacturing lot number of the lens, diopter power, and expiration date.

SYMBOL GLOSSARY

Comprehensive guide to symbols appearing on product label and cartons.

Symbol	Symbol Title	Symbol Description	Standard Reference	Title and Designation Number of the Standard
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1	**ISO 15223-1:2016** Medical device - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.	5.1.2	
	Date of manufacture	Indicates the date when the medical device was manufactured.	5.1.3	
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4	
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	
	Sterilized using steam	Indicates a medical device that has been sterilized using steam.	5.2.5	
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8	
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2	
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3	
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4	
$DIA\ \emptyset_T$	Total diameter	Indicates total diameter of lens	N/A	N/A
BC	Base curve	Indicates base curve of lens	N/A	N/A
$PWR\ F'_V$	Paraxial back vertex power	Indicates lens power in diopters	N/A	N/A
SPH	Sphere power	Indicates spherical power in diopters	N/A	N/A
AX	Axis power	Indicates axis power in degrees	N/A	N/A
CYL	Cylinder power	Indicates cylindrical power in diopters	N/A	N/A
ADD	Add power	Indicates additional power in diopters	N/A	N/A
YYYY-MM	Effective date	Indicates the date in which the insert revision was made effective	N/A	ISO 8601-1:2019 Date and time – Representations for information interchange – Part 1: Basic rules
	Prescription only (USA)	Indicates that federal law (U.S.) restricts this device to sale by or on the order of a licensed practitioner	N/A	21 CFR 801.109
	CE number	Indicates the CE Conformity Marking and the Notified Body Number	N/A	MDR 2017/745, Article 20, 3
	Green dot	Indicates paid fee to meet EU packaging directive	N/A	94/62/EC
	Medical device	Indicates the item is a medical device	N/A	N/A